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(54) Title: UNIFIED MANAGEMENT OF RADIOPHARMACEUTICAL DISPENSING, ADMINISTRATION, AND IMAGING

(57) Abstract: Apparatus is provided for use with at least one labeled radiopharmaceutical agent, the apparatus including a container (22) containing the at least one labeled radiopharmaceutical agent, and a portable computer-communicatable data carrier (120, 24) associated with the container (22), the data carrier (120, 24) containing imaging protocol information for use with the at least one labeled radiopharmaceutical agent. Other embodiments are also described.

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UNIFIED MANAGEMENT OF RADIOPHARMACEUTICAL DISPENSING,
ADMINISTRATION, AND IMAGING

CROSS-REFERENCES TO RELATED APPLICATIONS

The present patent application is a continuation-in-part of:

5 (i) International Application PCT/IL2005/001215, filed November 16, 2005;
and
10 (ii) International Application PCT/IL2005/001173, filed November 9, 2005,
which:
15 (a) claims the benefit of the following US Provisional Patent Applications:
• 60/625,971, filed November 9, 2004;
• 60/628,105, filed November 17, 2004;
• 60/630,561, filed November 26, 2004;
• 60/632,236, filed December 2, 2004;
• 60/632,515, filed December 3, 2004;
20 • 60/635,630, filed December 14, 2004;
• 60/636,088, filed December 16, 2004;
• 60/640,215, filed January 3, 2005;
• 60/648,385, filed February 1, 2005;
• 60/648,690, filed February 2, 2005;
25 • 60/675,892, filed April 29, 2005;
• 60/691,780, filed June 20, 2005;
• 60/700,318, filed July 19, 2005;
• 60/700,299, filed July 19, 2005;
• 60/700,317, filed July 19, 2005;
30 • 60/700,753, filed July 20, 2005;
• 60/700,752, filed July 20, 2005;

- 60/702,979, filed July 28, 2005;
- 60/720,034, filed September 26, 2005;
- 60/720,652, filed September 27, 2005; and
- 60/720,541, filed September 27, 2005, and

5 (b) is a continuation-in-part of the following International Patent Applications:

- PCT/IL2005/000572, filed June 1, 2005; and
- PCT/IL2005/000575, filed June 1, 2005.

The present patent application claims the benefit of the following US Provisional Applications:

10

- 60/750,287, filed December 13, 2005;
- 60/750,334, filed December 15, 2005; and
- 60/750,597, filed December 15, 2005.

The present patent application is related to a US provisional patent application filed on even date herewith, entitled, "Imaging protocols."

15 All of the above-mentioned applications are assigned to the assignee of the present application and are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to pharmaceutical management and control, and specifically to systems and methods for radiopharmaceutical dispensing, 20 administration, and imaging.

BACKGROUND OF THE INVENTION

US Patent Application Publication 2005/0277833 to Williams, Jr., which is incorporated herein by reference, describes techniques for handling, mixing, dispensing and/or injecting a mixture into an individual during a medical procedure. The mixture 25 contains pharmaceutical agents and/or radiopharmaceutical agents. Also described is a mixing device capable of diluting a radiopharmaceutical agent with, for instance, a diluent, for altering a radiation dose emitted by the radiopharmaceutical agent.

US Patent Application Publication 2005/0203389 to Williams, Jr., which is incorporated herein by reference, describes techniques for an operator to control an injection device and imaging equipment from a common control console. The injection device may be used to administer a contrast medium into a patient so that imaging equipment can acquire internal images of the patient. An injection system is bundled with software and/or hardware that is used to modify an existing imaging control console so that it can be used to operate both the injection device and imaging device. In one embodiment, the common control console can access stored protocols that can contain operational parameters for the injection device, the imaging device, or both.

US Patent 4,679,142 to Lee, which is incorporated herein by reference, describes techniques for dispersing quantities of radioactive material at a user location. Billing is accomplished by monitoring the decay of material and the degree of activity following each user withdrawal.

US Patent Application Publication 2005/0261938 to Silverbrook et al., which is incorporated herein by reference, describes a method for authenticating a pharmaceutical product, the pharmaceutical product being associated with packaging having disposed thereon or therein coded data including a number of coded data portions, each coded data portion being indicative of an identity of the pharmaceutical product and at least part of a digital signature of at least part of the identity. The method includes having a computer system receive indicating data from a sensing device, the sensing device being responsive to sensing of the coded data to generate indicating data at least partially indicative of the identity of the pharmaceutical product and the signature part. The computer system determines the identity at least one determined signature part and uses these to authenticate the pharmaceutical product.

US Patent Application Publication 2005/0261936 to Silverbrook et al., which is incorporated herein by reference, describes a method for allowing a user to interact with a pharmaceutical product, the pharmaceutical product associated with packaging having disposed thereon or therein coded data, at least some of the coded data being indicative of at least an identity. The method includes having a computer system receive indicating data from a sensing device, in response to sensing of the coded data, and determine, using the indicating data, at least one action. The computer system then performs the action associated with the pharmaceutical product, the action including at least one of providing

information to a user; updating tracking information relating to the pharmaceutical product; performing a transaction relating to the pharmaceutical product; authenticating the pharmaceutical product; and receiving feedback from the user.

US Patents 5,882,338 and 6,019,745 to Gray, which are incorporated herein by reference, describe a medical syringe comprising a cylindrical barrel having therein a plunger which can be axially driven by a plunger rod. The plunger rod passes through an aperture in the center of a finger grip having two finger grip projections at opposite sides thereof. A data carrier means in the form of an electrically or magnetically operable device is mounted near the end of one of the two finger grip projections, with preferably a device mounted near the end of each finger grip projection. The device carries data relating to the medicament contained or to be contained within the syringe, and can be read by a suitably adapted syringe pump when the syringe is mounted thereon to be driven by the syringe pump.

US Patent 6,970,735 to Uber, III et al., which is incorporated herein by reference, describes a system for producing a contrast-enhanced medical image of a patient, including a source of a contrast or enhancement medium, a pressurizing unit in fluid connection with the source of contrast or enhancement medium, an energy source operable to apply energy to a region of the patient, an imaging unit providing a visual display of an internal view of the patient based upon a signal resulting from the energy applied to the region of the patient, and a control unit. In an embodiment, the signal is affected by a condition of the contrast or enhancement medium in the patient. To control an imaging procedure, the control unit adjusts the condition of the contrast or enhancement medium in the patient based upon the signal. A communication interface preferably enables information between an injector subsystem and an imaging subsystem.

US Patents 5,781,442, 6,671,563, 6,915,170, and 6,731,989 to Engleson et al., which are incorporated herein by reference, describe a care management system in which the management of the administration of care for patients is automated. Hospital information systems are monitored and the information from those systems is used in verifying the administrations of care to patients. The care management system monitors ongoing administrations for progress and automatically updates records and provides alarms when necessary. The care management system is modular in nature but is fully integrated among its modules. Particular lists of data, such as the termination times of all

ongoing infusions, provide hospital staff current information for increased accuracy and efficiency in planning. Features include the automatic provision of infusion parameters to pumps for accurate and efficient configuration of the pump, and providing an alarm when an unscheduled suspension of an infusion exceeds a predetermined length of time. A 5 passive recognition system for identifying patients and care givers is described.

US Patent Application Publication 2003/0055685 to Cobb et al., which is incorporated herein by reference, describes techniques for monitoring administration of a medical product within a delivery device using a medicine data storage device attached to the delivery device, which includes a product identifier identifying the medical product 10 and an intended patient identifier identifying a patient intended to receive the medical product. Before administering the medical product to an individual patient, the product identifier and the intended patient identifier are uploaded into a reader, and a patient identifier is accessed from the reader's memory or uploaded from a patient identification device associated with the individual patient into the reader. The patient identifier is 15 compared with the intended patient identifier to determine whether the individual patient is intended to receive the medical product. Once it is confirmed that the individual patient is intended to receive the medical product, the medical product is administered to the individual patient.

US Patent Application Publication 2005/0131270 to Weil et al., which is incorporated herein by reference, describes a system including a radiation treatment agent 20 to treat tissue in response to received X-ray radiation and an identifier associated with the radiation treatment agent. The identifier may be usable to identify a radiation treatment plan. In some embodiments, a radiation treatment plan associated with a patient is generated, the radiation treatment plan is associated with an identifier and a patient 25 identifier identifying the patient, a radiation treatment agent is prepared for delivery to the patient according to the radiation treatment plan, and the radiation treatment agent is associated with the identifier.

US Patent 6,985,870 to Martucci et al., which is incorporated herein by reference, describes a medication delivery system comprising a medical container holding a 30 prescribed medication to be delivered to a patient, a tag adapted to be worn by the patient, a handheld computing device, and an electronic medication delivery device. Data on the medication is contained in a first label on the medication container. The first label also

contains the instruction on how the medication is delivered to the patient, including the appropriate settings for an electronic medication delivery device for delivering the medication to the patient. Patient data is contained in a second label on the tag worn by the patient. The medication data, medication delivery instruction, and patient data are 5 provided in machine readable formats. The handheld computing device reads the medication data and the medication delivery instruction on the medication container and the patient data on the patient tag. The handheld computing device stores the information obtained and performs a matching check to confirm that the medication data matches with the patient data. Upon a confirmed match, it transmits the medication delivery instruction 10 to the electronic medication delivery device, which downloads the instruction, programs the delivery device, and prompts an operator to begin delivering the medication to the patient according to the downloaded instruction.

US Patent Application Publication 2005/0029277 to Tachibana, which is incorporated herein by reference, describes a drug container having an identification tag 15 fixed or detachably provided at a predetermined position of the container, the tag having recorded thereon drug data on a kind and a concentration of a drug, and upper and/or lower limits of a flow rate for continuous infusion, or time and flow rate for one-shot administration.

US Patent Application Publication 2005/0277911 to Stewart et al., which is 20 incorporated herein by reference, describes techniques for programming a medical therapy in a medical device. The medical device has a controller, a memory, a processor, and an input device. The memory is preloaded with at least one of a plurality of patient profiles and condition profiles. The memory is further preloaded with an associated medication therapy for a plurality of the profiles. The input device receives profile data, 25 comprising at least one of a patient profile data and a condition profile data for a specific patient, and the processor processes the received profile data and provides as output one of the preloaded medication therapies based on the processed profile data.

US Patent 6,506,155 to Sluis, which is incorporated herein by reference, describes 30 an ultrasound imaging system including a data entry device that reads storage media that is assigned to each patient on which the system is to be used or the operator of the system to obtain ultrasound images. The storage media, which comprises a barcode, smartcard, or personal digital assistant, contains patient identifying information. The patient or

procedure identifying information is used to access a digital requisition that is referenced by the patient identifying information. The digital requisition is stored in a disk drive included in the ultrasound imaging system or in a clinical information system accessed through a communication link included in the ultrasound imaging system. The digital 5 requisition includes information pertaining to an ultrasound examination procedure that is to be performed on the patient, which is used to automatically set up the ultrasound imaging system. The digital requisition may also include the patient's medical history or information about the patient that can be associated with ultrasound images obtained from the patient.

10 US Patent Application Publication 2005/0121505 to Metz et al., which is incorporated herein by reference, describes patient-centric data acquisition protocol selection systems and methods, and identification tags therefor. A patient-centric data acquisition protocol selection system comprises a programmable identification tag capable of allowing predetermined information about a patient to be stored therein and 15 retrieved therefrom; a medical imaging system capable of communicating with the programmable identification tag; and programming associated with the medical imaging system for selecting an optimal data acquisition protocol. The medical imaging system reads information from the programmable identification tag and then the programming selects an optimal data acquisition protocol based, at least in part, on the predetermined 20 information about the patient that is stored in the programmable identification tag.

PCT Publication WO 04/004787 to Van Naemen et al., which is incorporated herein by reference, describes a method for dispensing individual doses of a radiopharmaceutical solution, which consists of a radioactive parent solution diluted with a diluting solution. Also described is a computer-generated dose dispenser for dispensing 25 individual doses of a radiopharmaceutical solution at a specified speed. The method and device are described as being particularly suitable for use in the field of nuclear medicine, and more in particular for use for PET scan applications.

US Patent 6,032,155 to de la Huerga, which is incorporated herein by reference, describes techniques for administering a prescribed medication to a patient. A medication 30 administration system and apparatus dispense the prescribed medication, verify that the medication is given to a correct patient by an authorized healthcare worker, and track and record the administration of the medication. The system utilizes a workstation connected

to a database containing prescribed medication dose information for various patients. A healthcare worker uses the workstation to manually or automatically dispenses the medication the portable container. An information device is secured to the portable container during transport and administration of the medication to the intended patient.

5 The information device prevents access to the medication or warns the healthcare worker of a potential error if the medication is delivered to the wrong patient or administered by an unauthorized healthcare worker. The information device records actual consumption information, and delivers this information back the workstation database or to a hospital or pharmacy database.

10 US Patent 5,317,506 to Coutre et al., which is incorporated herein by reference, describes an infusion management and pumping system. Infusion prescriptions are generated and monitored by a pharmacy management system. Labels for each infusion to be given to a patient are generated and printed in a barcode format. Each label contains data regarding a prescribed infusion program, including the drug or drugs to be infused, 15 the infusion regimen, the expiration date, and the patient to whom the infusion is to be administered. The management system checks for incompatibilities between drugs that are being prescribed for simultaneous infusion. Each label generated by the management system is attached to the container which holds the infusion solution. The data on the label is transferred to an infusion pumping system by a barcode reader at the infusion pumping system. The pumping system checks that all necessary data has been entered. 20 During operation, the pumping system checks for a variety of alarm conditions and stores any alarms in a ranking according to urgency. The infusion pumping system is responsive to remote or biofeedback instructions to alter the planned infusion program. Central computer records processing receives infusion data and provides infusion, 25 inventory, and use analysis.

US Patent 5,039,863 to Matsuno et al., which is incorporated herein by reference, describes an automatic radioisotope filling apparatus, which is equipped with a radioisotope vial containing a radioisotope solution, a saline vial containing a physiological saline solution, a dilution vial to which a predetermined amount of the 30 radioisotope solution and a predetermined amount of the physiological saline solution are to be transferred to prepare a diluted radioisotope solution, a radiation detector for measuring the radioactive intensity of the diluted radioisotope solution prepared in the dilution vial, and a plurality of label vials containing a drug to be labeled.

US Patent Application Publication 2004/0051368 to Caputo et al., which is incorporated herein by reference, describes a system for delivering medical fluid to a patient. The system includes a medical container including a Radio Frequency Identification (RFID) tag storing data related to the medical fluid therein. A RF reader 5 receives data signals transmitted from the RFID tag that include a desired flow rate for delivering the fluid to the intended patient. A pump coupled to the reader includes a pumping mechanism for pumping the medical fluid from the container, and a pump controller for receiving the data including the desired flow rate from the reader. The pump controller automatically controls the pumping mechanism to pump the medical 10 fluid from the medical container at the desired flow rate based upon the data.

US Patent Application Publication 2005/0171815 to Vanderveen, which is incorporated herein by reference, describes a centralized medication management system for monitoring, managing and controlling medication delivery from a central location. A central computer displays medication orders and ongoing medication administrations for 15 a health care facility. The central computer checks medication delivery against a database of medication administration guidelines, including guidelines for medication interactions with other medications and with patient conditions, and provides an indication of any detected incompatibilities. A clinician at the central location may adjust the medication administration parameters in response to detected incompatibilities and communicate 20 with a caregiver at the point of care to provide decision support. In an embodiment, the central location is a pharmacy at the healthcare facility.

US Patent Application Publication 2005/0240441 to Suzuki, which is incorporated herein by reference, describes a hospital information system. The system enables an RF reader, comprising a personal digital assistant (PDA), to read tag information recorded by 25 RF tags either attached to, or embedded in, various types of a patient wrist bands, injection medicine bottles, patient charts, and medical instrument cases. The PDA transmits a query to a server via a wireless LAN for confirmation from the server. The server collates the query with the content of a medical practice order recorded in its data base, and registers a completion of instructed operation for an instructed item in the 30 database, and replies with a notification if the transmitted readout data from the PDA is correct. If the readout data is incorrect, the PDA is notified and instructed to perform another reading.

US Patent Application Publication 2001/0049608 to Hochman, which is incorporated herein by reference, describes an automated drug administering system such an injection device or infusion pump, which is provided with means for reading information from a container holding the drug. The information is then checked for 5 accuracy before the administration of the drug. Optionally, an ID tag on the patient and/or the health care professional providing the drug may also be scanned and checked. The information thus gathered is sent to another station where it is logged for future use and analyzed.

US Patent 6,743,202 to Hirschman et al., which is incorporated herein by 10 reference, describes apparatus for sharing information on syringe configuration between syringes and injector systems, comprising a storage system to store encoded information on syringe configuration. The encoded information is readable by a detection circuit in an injector. In one embodiment, the storage system is an electronic storage system in which information relevant to the syringe configuration is encoded. A method comprises 15 the step of conveying syringe configuration information to a detector in an injector for use with the syringe.

US Patent Application Publication 2005/0148869 to Masuda, which is incorporated herein by reference, describes a liquid syringe having various kinds of data 20 items recorded in a two-dimensional code format. A liquid injector optically reads the two-dimensional codes, decodes them, and executes a predetermined operations corresponding to the decoded results. Recording, for example, a variable pattern for the liquid of interest in the two-dimensional code format on the liquid syringe makes it possible for the liquid injector to inject the liquid in accordance with the predetermined 25 variable pattern.

US Patent 6,346,886 de la Huerga, which is incorporated herein by reference, 25 describes an electronic identification apparatus having data storage memory on board a removable transceiver device. The transceiver device also includes a processor and a transponder for receiving information pertaining to the object/person to which it is attached and storing the information in memory. The transceiver also transmits stored 30 data to a control computer or the external devices. The transceiver is mounted on a base, such as a wristband, and the apparatus includes an attachment sensor indicating whether the transceiver is attached to the base. If the transceiver has been removed from the base,

the processor performs one or more lockdown operations to prevent the stored data from being used in connection with another object or person. The lockdown operations include clearing the contents of the memory, disabling access to the memory, suppressing the display of stored data and activating an alarm.

5 US Patent Application Publication 2004/0156081 to Bril et al., which is incorporated herein by reference, describes a color-coded signature, for securing documents or encrypting images. The encrypted image comprises an array of printed positions formed using a group of inks each of which has a predetermined spectrum. The positions are selected to form a predetermined image, either real or virtual, when the
10 image is viewed through an optical processor. The optical processor may further use a distorted grating or a distorted lens. The correct image is the spectrum, as distorted by the optical processor. An image formed using inks having the same colors as experienced by the human eye, or even by a standard spectrometer will fail to form the correct predetermined image.

15 The following patents and patent application publications, all of which are incorporated herein by reference, may be of interest:

US Patent Applications 2005/0131579 and 2005/0088306, and US Patent 6,935,560, all to Andreasson

US Patent 6,851,615 to Jones

20 US Patent application 2005/0131397 and US Patent 6,861,954 to Levin

US Patent 6,519,569 to White et al.

US Patent 5,692,640 to Caulfield et al.

US Patents 6,475,192 and 6,733,478 to Reilly et al.

US Patent 6,958,053 to Reilly

25 US Patent Application Publications 2005/0261937 and 2005/0261938 to Silverbrook et al.

US Patent 6,994,249 to Peterka et al.

US Patent 6,843,357 to Bybee et al.

US Patent 6,425,174 to Reich

- US Patent 6,722,499 to Reich
- US Patent 5,536,945 to Reich
- US Patent RE36,693 to Reich
- US Patent 5,519,931 to Reich
- 5 US Patent Application Publication 2005/0198800 to Reich
- US Patent 6,576,918 to Fu et al.
- US Patent Application Publication 2005/0247893 to Fu et al.
- US Patent 5,927,351 to Zhu et al.
- US Patent 5,828,073 to Zhu et al.
- 10 US Patent 6,162,198 to Coffey et al.
- US Patents 6,338,007 and 6,116,461 to Broadfield et al.
- US Patent 5,944,190 to Edelen
- PCT Publication WO 04/032151 to Bising et al.
- US Patent Application Publication 2005/0234424 to Bising et al.
- 15 US Patent 4,296,785 to Vitello et al.
- US Patent 3,446,965 to Ogier et al.
- US Patent 6,355,024 to Small et al.
- US Patent 6,468,261 to Small et al.
- US Patent 5,580,541 to Wells et al.
- 20 US Patent 3,535,085 to Shumate
- US Patent 4,853,546 to Abe et al.
- US Patent 5,329,976 to Haber et al.
- US Patent 5,304,165 to Haber et al.
- US Patent 5,911,252 to Cassel
- 25 US Patent 5,475,232 to Powers et al.
- PCT Publication WO 05/002971 to Tochon-Danguy et al.

US Patent Application Publication 2005/0278066 to Graves

US Patent 5,479,969 to Hardie et al.

US Patent 5,309,959 to Shaw et al.

US Patent 6,870,175 to Dell et al.

5 US Patent 6,767,319 to Reilly et al.

US Patent 6,976,349 to Baldwin et al.

US Patent 6,957,522 to Baldwin et al.

US Patent 6,915,619 to Baldwin

US Patent 6,813,868 to Baldwin et al.

10 US Patent 5,893,397 to Peterson et al.

US Patents 5,885,216, 5,806,519, and 6,901,283 to Evans, III et al.

US Patent Application Publication 2004/0084340 to Morelle et al.

US Patent 6,269,340 to Ford et al.

US Patent Application Publication 2004/0193453 to Butterfield et al.

15 US Patent 4,476,381 to Rubin

US Patent 6,643,537 to Zatezalo et al.

US Patent Application Publication 2005/0108044 to Koster

US Patent 6,851,615 to Jones

US Patent 5,840,026 to Uber, III et al.

20 US Patent 6,685,678 to Evans et al.

US Patent Application Publication 2003/0183226 to Brand et al.

US Patent Application Publications 2005/0107914 and 2005/0113945 to Engleson et al.

25 US Patent Application Publication 2002/0198738 to Osborne

US Patent Application Publication 2002/0099334 to Hanson et al.

US Patents 6,317,648 and 6,522,945 to Sleep et al.

US Patent 6,155,485 and 6,318,630 to Coughlin et al.
US Patent 6,202,923 to Boyer et al.
US Patent 6,915,823 to Osborne et al.
US Patent Application Publication 2004/0205343 to Forth et al.

5 US Patent 5,493,805 to Penuela et al.

US Patent 5,973,598 to Beigel

US Patent Application Publication 2005/0149350 to Kerr et al.

US Patent 5,884,457 to Ortiz et al.

10 The following patents and patent application publications, which describe gamma cameras and imaging processing techniques, and which are incorporated herein by reference, may be of interest:

US Patent Application Publication 2005/0205792 to Rousso et al.

PCT Publication WO 05/118659 to Dichterman et al.

PCT Publication WO 05/119025 to Nagler et al.

15 US Patent Application Publication 2004/0204646 to Nagler et al.

PCT Publication WO 04/042546 to Kimchy et al.

US Patent Application Publication 2004/0054248 to Kimchy et al.

US Patent Application Publication 2004/0015075 to Kimchy et al.

US Patent Application Publication 2004/0054278 to Kimchy et al.

20 US Patent Application Publication 2005/0266074 to Zilberstein et al.

US Patents 5,939,724, 5,587,585, and 5,365,069 to Eisen et al.

US Patent 6,943,355 to Shwartz et al.

US Patents 6,242,743 and 5,757,006 to DeVito et al.

US Patent 6,137,109 to Hayes

25 US Patent 6,388,258 to Berlad et al.

US Patent 6,429,431 to Wilk

US Patent 6,838,672 to Wagenaar et al.

US Patents 6,740,882, 6,545,280, 6,229,145, 5,519,221, and 5,252,830 to Weinberg

US Patent 6,713,766 to Garrard et al.

5 US Patent 6,765,981 to Heumann

US Patent 6,664,542 to Ye et al.

US Patent 6,080,984 to Friesenhahn

US Patent 5,818,050 to Dilmanian et al.

US Patent 6,728,583 to Hallett

10 US Patent 5,481,115 to Hsieh et al.

US Patent 6,723,988 to Wainer

US Patent 6,940,070 to Tumer

US Patent 6,635,879 to Jimbo et al.

US Patent 6,353,227 to Boxen

15 US Patent 6,184,530 to Hines et al.

US Patent Application Publication 2005/0145797 to Oaknin et al.

US Patent Application Publication 2004/0251419 to Nelson et al.

US Patent Application Publication 2003/0001098 to Stoddart et al.

PCT Publication WO 98/16852 to DeVito et al.

20 PCT Publication WO 05/059840 to Nielsen et al.

SUMMARY OF THE INVENTION

In some embodiments of the present invention, an end-to-end automated system for medical imaging comprises a plurality of integrated elements that are configured to electronically exchange information among one another. The elements include an 25 automated radiopharmaceutical dispensing system, a portable information-bearing radiopharmaceutical agent container, a patient management system, a portable patient-specific data carrier, an automated administration system, and an automated

imaging system. The systems perform their respective automated functions at least in part responsively to the exchanged information. The elements typically authenticate one another via the exchanged information, in order to ensure that only authorized elements participate in the system, and that the systems perform only authorized and appropriate 5 functions.

The exchanged information typically includes patient-specific data, radiopharmaceutical agent-specific data, and/or patient- or radiopharmaceutical agent-specific imaging protocol data. Such data enable the systems to customize their respective automated functions for specific patients, radiopharmaceutical agents, 10 indications, and/or imaging procedures. For some applications, the exchanged information includes commercial license information relating to the use of a specific protocol with a specific radiopharmaceutical agent, and one or more of the systems are configured to verify the license information before performing their respective functions.

In some embodiments of the present invention, the information-bearing 15 radiopharmaceutical agent container and/or the patient-specific data carrier is configured to contain protocol information for performing an imaging procedure using the labeled radiopharmaceutical agent held by the container. For some applications, the protocol information includes SPECT imaging protocol information, and the imaging system uses the protocol information to perform a SPECT imaging procedure using the labeled 20 radiopharmaceutical agent contained in the container. For some applications, the agent container contains a single dose of the labeled radiopharmaceutical agent, which dose is appropriate for use with the imaging protocol.

In some embodiments of the present invention, the information-bearing radiopharmaceutical agent container or the patient-specific data carrier is configured to 25 contain at least one kinetic parameter of the labeled radiopharmaceutical agent contained in the container. The imaging system uses the kinetic parameter to perform a dynamic SPECT imaging procedure.

In some embodiments of the present invention, the information-bearing radiopharmaceutical agent container contains radiopharmaceutical information regarding 30 the labeled radiopharmaceutical agent contained in the container. The portable patient-specific data carrier is configured to contain patient information regarding the patient, and imaging protocol information for use with the labeled radiopharmaceutical

agent, such as SPECT imaging protocol information. The imaging system uses the protocol information to perform an imaging procedure, such as a dynamic SPECT imaging procedure. For some applications, the patient-specific data carrier comprises a coupling mechanism configured to be coupled to the patient. For example, the coupling mechanism may comprise a bracelet, a watch, a necklace, or another wearable article.

In some embodiments of the present invention, the information-bearing radiopharmaceutical agent container contains a first identifier value, and the patient-specific data carrier contains a second identifier value. The imaging system is configured to perform an imaging procedure responsively to a detection of a correspondence between the first and second identifier values. For some applications, the first identifier value equals the second identifier value, while for other applications the values do not equal one another, but instead correspond to one another based on information provided by an element of the end-to-end system. For some applications, the first and/or second identifier values are arbitrarily assigned, or pre-loaded into the data carrier by a manufacturer or distributor, while for other applications at least one of the identifier values comprises a patient identifier, or another meaningful value. For some applications, at least one of the information-bearing agent container and the patient-specific data carrier performs the detection of the correspondence, while for other applications the imaging system or another element of the end-to-end system performs the detection of the correspondence.

In some embodiments of the present invention, the imaging system comprises a SPECT imaging system configured to utilize the information contained in the labeled radiopharmaceutical agent container and/or the patient-specific data carrier to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

The integration of the elements of the end-to-end system, and the exchange of authenticatable information among the elements generally increase patient safety, by ensuring that each patient receives the prescribed labeled radiopharmaceutical agent and dosage, and undergoes the desired imaging protocol. For some applications, one or more

elements of the end-to-end system are configured to perform their respective function only upon being triggered by another element of the system. For example, the administration or imaging system may perform its function only upon being triggered by the information-bearing radiopharmaceutical agent container, by the patient-specific data 5 carrier, and/or, in the case of the administration system, by the imaging system.

In some embodiments of the present invention, the automated radiopharmaceutical dispensing system comprises an information manager that is configured to receive radiopharmaceutical information regarding a labeled radiopharmaceutical agent and patient information regarding a patient. Responsively to the information, the dispensing 10 system automatically dispenses a dose of the labeled radiopharmaceutical agent to an agent container, and stores the radiopharmaceutical information and at least a portion of the patient information in a data carrier associated with the container. For some applications, the radiopharmaceutical information is selected from the group consisting of: imaging protocol information for use with the labeled radiopharmaceutical agent, such 15 as a SPECT imaging protocol; at least one kinetic parameter useful for performing a dynamic SPECT imaging procedure using the at least one labeled radiopharmaceutical agent; and authenticatable information regarding a commercial license for use of a SPECT imaging protocol with the at least one labeled radiopharmaceutical agent.

In some embodiments of the present invention, the dispensing system is 20 configured to receive a mother vial containing a labeled radiopharmaceutical agent in a quantity sufficient for preparation of a plurality of doses of the labeled radiopharmaceutical agent. Associated with the mother vial is a data carrier containing information regarding the labeled radiopharmaceutical agent, such as the formulation, radioactivity information, and protocol information. The information manager of the 25 dispensing system receives at least a portion of the labeled radiopharmaceutical agent information from the data carrier.

In some embodiments of the present invention, use of the end-to-end automated system enables customization of one or more aspects of the imaging process, from dispensing to diagnosis. Customization typically includes one or more of the following:

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- The dispensing system customizes the dispensed dose for a specific patient, based on radiopharmaceutical information and patient-specific information. Typically, the dispensing system customizes the dispensed

dose (e.g., the radioactivity level thereof) based in part on the scheduled time of the scheduled time of administration of the dose, and/or the scheduled time of the imaging procedure to be performed using the dose.

- The administration system customizes the administered dose for a specific patient, based on radiopharmaceutical information and patient-specific information. For some applications in which the administration system customizes the administered dose, the radiopharmaceutical agent container contains a standard, non-customized dose.
- The imaging system customizes image acquisition, image reconstruction, image analysis, and/or diagnosis, based on radiopharmaceutical information and patient-specific information, such as patient physiology and/or known and/or suspected disease of the patient.

Such customization is typically based at least in part on information provided by the manufacturer or distributor of the radiopharmaceutical agent. Such information may be in the form of lookup tables and/or expert system rules.

As used in the present application, including in the claims, "labeled" means radiolabeled, and "unlabeled" means not radiolabeled.

There is therefore provided, in accordance with an embodiment of the present invention, apparatus for use with at least one labeled radiopharmaceutical agent, the apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent; and
a portable computer-communicatable data carrier associated with the container, the data carrier containing imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

For some applications, the apparatus comprises a device configured to write the imaging protocol information to the data carrier.

For some applications, the data carrier additionally contains administration protocol information useful for administering the at least one labeled radiopharmaceutical agent.

In an embodiment, the imaging protocol information comprises instructions for performing an imaging procedure using the at least one labeled radiopharmaceutical agent. Alternatively or additionally, the imaging protocol information comprises an identifier of an imaging protocol. Further alternatively or additionally, the imaging 5 protocol information comprises a parameter of the at least one labeled radiopharmaceutical agent. Still further alternatively or additionally, the imaging protocol information comprises a parameter useful for configuring at least one aspect of an imaging procedure performed using the at least one labeled radiopharmaceutical agent.

In an embodiment, the container contains a single dose of the radiopharmaceutical 10 agent, which dose is appropriate for use with the imaging protocol information. Alternatively, the container contains a plurality of labeled radiopharmaceutical agents mixed together. For some applications, the container is shaped so as to define a plurality of chambers, each of which contains a respective one of a plurality of labeled radiopharmaceutical agents.

15 In an embodiment, the data carrier comprises a first data carrier, which contains a first identifier value, the apparatus further comprises a second computer-communicatable data carrier, which contains a second identifier value, and the apparatus is configured to operate responsively to a detection of a correspondence between the first and second identifier values. For some applications, at least one of the first and second data carriers 20 is configured to perform the detection of the correspondence. Alternatively or additionally, the apparatus comprises a correspondence-detection element configured to perform the detection of the correspondence.

In an embodiment, at least one of the first and second data carriers contains an 25 identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

For some applications, at least one of the first and second identifier values comprises an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

In an embodiment, exactly one of the first and second data carriers comprises a 30 coupling mechanism configured to be coupled to a patient to whom the labeled radiopharmaceutical agent is to be administered.

In an embodiment, the apparatus comprises an imaging system comprising imaging functionality, the imaging system configured, responsively to the detection of the correspondence, to drive the imaging functionality to perform an imaging procedure using the at least one labeled radiopharmaceutical agent.

5 In an embodiment, the data carrier is physically coupled to the container. For some applications, the data carrier contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered, and the imaging protocol information comprises imaging protocol information selected for the patient. For some applications, the imaging protocol information comprises an identifier of an imaging protocol.

10 For some applications, the imaging protocol information comprises imaging protocol information customized for the patient.

In an embodiment, the imaging protocol information comprises SPECT imaging protocol information, such as dynamic SPECT imaging protocol information. For some applications, the SPECT imaging protocol information comprises at least one kinetic 15 parameter of the at least one labeled radiopharmaceutical agent, the at least one kinetic parameter useful for performing a dynamic SPECT imaging procedure using the at least one labeled radiopharmaceutical agent.

20 In an embodiment, the apparatus comprises an imaging system, which comprises a communication element, configured to read the imaging protocol information from the data carrier; and a control unit, comprising imaging functionality, which is configured to perform an imaging procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

25 In an embodiment, the imaging system comprises a camera, wherein the imaging functionality comprises image acquisition functionality, and wherein the image acquisition functionality is configured to perform an image acquisition procedure using the camera, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element. For some applications, the image acquisition functionality configures a total acquisition time of the 30 image acquisition procedure at least in part responsively to the imaging protocol information. Alternatively or additionally, the camera comprises a plurality of detectors, and wherein the image acquisition functionality is configured to configure, at least in part

responsively to the imaging protocol information, at least one motion of at least one of the detectors during the image acquisition procedure. For some applications, the control unit is configured to configure, at least in part responsively to the imaging protocol information, a waiting time between administration of the labeled radiopharmaceutical agent and commencement of the image acquisition procedure. For some applications, the image acquisition functionality is configured to perform a gated image acquisition procedure at least in part responsively to the imaging protocol information.

5 In an embodiment, the imaging functionality comprises image reconstruction functionality, and wherein the image reconstruction functionality is configured to perform an image reconstruction procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

10 In an embodiment, the imaging functionality comprises image analysis functionality, and wherein the image analysis functionality is configured to perform an image analysis procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

15 In an embodiment, the imaging functionality comprises diagnosis functionality, and wherein the diagnosis functionality is configured to perform a diagnostic procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

20 In an embodiment, the imaging procedure includes a three-dimensional dynamic imaging study, and wherein the imaging functionality is configured to perform the three-dimensional dynamic imaging study, and to configure the study at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

25 In an embodiment, the data carrier is not physically coupled to the container, and wherein the data carrier contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered. For some applications, the data carrier comprises a coupling mechanism configured to be coupled to the patient. In an embodiment, the data carrier comprises a first data carrier, and wherein the apparatus further comprises a second computer-communicatable data carrier physically coupled to

the container, the second data carrier containing radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent.

There is also provided, in accordance with an embodiment of the present invention, apparatus for use with at least one labeled radiopharmaceutical agent, the 5 apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent; and
a computer-communicatable data carrier associated with the container, the data carrier containing authenticatable information regarding a commercial license for use of SPECT imaging protocol information with the at least one labeled radiopharmaceutical 10 agent.

In an embodiment, the apparatus comprises an imaging system, which comprises:
a communication element, configured to read the authenticatable license information from the data carrier;
a control unit, comprising imaging functionality, the control unit configured to:
15 authenticate the authenticatable license information, and
only upon authentication, drive the imaging functionality to perform an imaging procedure using the SPECT imaging protocol information.

For some applications, the apparatus comprises a device configured to write the authenticatable license information to the data carrier.

20 For some applications, the data carrier is physically coupled to the container.

There is further provided, in accordance with an embodiment of the present invention, apparatus comprising a portable computer-communicatable data carrier containing authenticatable information regarding a commercial license for use of SPECT imaging protocol information.

25 For some applications, the data carrier additionally contains patient information regarding a patient upon whom an imaging procedure using the SPECT imaging protocol information is to be performed.

For some applications, the authenticatable license information is encrypted.

In an embodiment, the apparatus comprises an imaging system, which comprises:
30 a communication element, configured to read the authenticatable license

information from the data carrier;
a control unit, comprising imaging functionality, the control unit configured to:
authenticate the authenticatable license information, and
only upon authentication, drive the imaging functionality to perform an imaging
5 procedure using the SPECT imaging protocol information.

For some applications, the apparatus comprises a device configured to write the authenticatable license information to the data carrier.

For some applications, the data carrier comprises a coupling mechanism configured to be coupled to a patient upon whom an imaging procedure using the SPECT
10 imaging protocol information is to be performed.

There is still further provided, in accordance with an embodiment of the present invention, apparatus comprising:

a first portable computer-communicatable data carrier containing a first identifier value;
15 a second portable computer-communicatable data carrier containing a second identifier value; and
an imaging system comprising imaging functionality, the imaging system configured, responsively to a detection of a correspondence between the first and second identifier values, to drive the imaging functionality to perform an imaging procedure on a
20 patient.

For some applications, at least one of the first and second data carriers is configured to perform the detection of the correspondence. Alternatively or additionally, the imaging system comprises a correspondence-detection element configured to perform the detection of the correspondence.

25 For some applications, at least one of the first and second data carriers contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

For some applications, at least one of the first and second identifier values comprises an identifier of a patient to whom the labeled radiopharmaceutical agent is to
30 be administered.

In an embodiment, one of the first and second data carriers comprises a coupling

mechanism configured to be coupled to a patient to whom the labeled radiopharmaceutical agent is to be administered.

For some applications, the apparatus comprises a device configured to write at least one of the first and second identifier values to the respective first and second data carriers.

In an embodiment, at least one of the first and second data carriers contains radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent, the imaging system comprises a communication element, configured to read the radiopharmaceutical information from the at least one of the data carriers, and the imaging system is configured to configure the imaging procedure at least in part responsively to the read radiopharmaceutical information. For some applications, the apparatus comprises a container containing the at least one labeled radiopharmaceutical agent. For some applications, one of the first and second data carriers is physically coupled to the container.

In an embodiment, the imaging functionality comprises a nuclear camera. For some applications, the nuclear camera comprises a SPECT camera.

There is yet further provided, in accordance with an embodiment of the present invention, apparatus for use with first and second portable computer-communicatable data carriers containing first and second identifier values, respectively, the apparatus comprising an imaging system, which comprises:

imaging functionality; and

a control unit configured to drive the imaging functionality to perform an imaging procedure on a patient, responsively to a detection of a correspondence between the first and second identifier values.

For some applications, the imaging system comprises a correspondence-detection element configured to perform the detection of the correspondence.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for use with at least one labeled radiopharmaceutical agent for administration to a patient, the apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent; a first computer-communicatable data carrier physically coupled to the container,

the first data carrier containing radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent; and

5 a second portable computer-communicatable data carrier containing patient information regarding the patient, and imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

For some applications, the imaging protocol information comprises SPECT imaging protocol information.

For some applications, the patient information comprises an identifier of the patient.

10 For some applications, the second data carrier comprises a coupling mechanism configured to be coupled to the patient.

For some applications, the first data carrier contains a first patient identifier, the patient information contained in the second data carrier comprises a second patient identifier, and the apparatus comprises an administration system, which comprises:

15 a first communication element, configured to read the first patient identifier from the first data carrier;

a second communication element, configured to read the second patient identifier from the second data carrier; and

20 a control unit, configured to compare the first patient identifier to the second patient identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

25 For some applications, the first data carrier contains a first protocol identifier, the imaging protocol information contained in the second data carrier comprises a second protocol identifier, and the apparatus comprises an administration system, which comprises:

a communication element, configured to read the first and second protocol identifiers from the first and second data carriers, respectively; and

30 a control unit, configured to compare the first protocol identifier to the second protocol identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

For some applications, the first data carrier contains a first protocol identifier, the imaging protocol information contained in the second data carrier comprises a second protocol identifier, and the apparatus comprises an administration system, which comprises:

- 5 a first communication element, configured to read the first protocol identifier from the first data carrier;
- a second communication element, configured to read the second protocol identifier from the second data carrier; and
- a control unit, configured to compare the first protocol identifier to the second protocol identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

In an embodiment, the apparatus comprises an administration system, which comprises:

- 15 a communication element; and
- a control unit, configured to:
 - generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container, and
 - drive the communication element to transmit information regarding the administration to the second data carrier.

For some applications, the apparatus comprises a device configured to write the imaging protocol information to the first data carrier. Alternatively or additionally, the apparatus comprises a device configured to write the patient information to the second data carrier.

- 25 In an embodiment, the imaging protocol information comprises imaging protocol information selected for the patient. For some applications, the imaging protocol information comprises an identifier of an imaging protocol. For some applications, the imaging protocol information comprises imaging protocol information customized for the patient.
- 30 In an embodiment, the first data carrier contains a first patient identifier, the patient information contained in the second data carrier includes a second patient identifier, and the apparatus comprises an administration system, which comprises:

a communication element, configured to read the first and second patient identifiers from the first and second data carriers, respectively; and

5 a control unit, configured to compare the first patient identifier to the second patient identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

For some applications, the administration system comprises an automated administration device, configured to administer the at least one labeled radiopharmaceutical agent to the patient upon being triggered by the administration 10 signal.

For some applications, the control unit is configured to generate the administration signal to trigger the administration of the at least one labeled radiopharmaceutical agent by instructing a healthcare worker to administer the at least one labeled radiopharmaceutical agent to the patient.

15 There is yet additionally provided, in accordance with an embodiment of the present invention, apparatus for use with at least one labeled radiopharmaceutical agent for administration to a patient, the apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent;
20 a computer-communicatable data carrier associated with the container, the data carrier containing data regarding at least one of: the labeled radiopharmaceutical agent and the patient; and
a SPECT imaging system comprising:

a communication element, configured to read the data; and
25 a control unit, configured to utilize the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

30 For some applications, the data carrier contains the data regarding the labeled radiopharmaceutical agent. Alternatively or additionally, the data carrier contains the data regarding the patient.

For some applications, the control unit is configured to utilize the read data to customize the administration of the labeled radiopharmaceutical agent. Alternatively or additionally, the control unit is configured to utilize the read data to customize the acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered. Further alternatively or additionally, control unit is configured to utilize the read data to customize the reconstruction of the SPECT image. Still further alternatively or additionally, the control unit is configured to utilize the read data to customize the analysis of the SPECT image. Alternatively or additionally, the control unit is configured to utilize the read data to customize the diagnosis of a condition of the patient based at least in part on the analysis.

For some applications, the apparatus comprises a device configured to write the data to the data carrier.

There is also provided, in accordance with an embodiment of the present invention, a SPECT imaging system for use with a container containing at least one labeled radiopharmaceutical agent for administration to a patient, and data regarding at least one of: the labeled radiopharmaceutical agent and the patient, the system comprising:

a communication element, configured to read the data; and
a control unit, configured to utilize the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

For some applications, the system comprises a device configured to write the data to the container.

There is further provided, in accordance with an embodiment of the present invention, an automated radiopharmaceutical dispensing system for use with a container and a computer-communicatable container data carrier associated with the container, the system comprising:

a robot, configured to manipulate the container;

a communication element; and
a control unit, configured to:

receive radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent, the radiopharmaceutical information selected from the group 5 consisting of: imaging protocol information for use with the at least one labeled radiopharmaceutical agent, and authenticatable information regarding a commercial license for use of an imaging protocol with the at least one labeled radiopharmaceutical agent,

receive patient information regarding a patient,
10 drive the robot to automatically dispense a dose of the labeled radiopharmaceutical agent to the container, and

drive the communication element to transmit to the container data carrier at least a portion of the radiopharmaceutical information and at least a portion of the patient information.

15 For some applications, the control unit is configured to receive the radiopharmaceutical information regarding a plurality of labeled radiopharmaceutical agents, and drive the robot to automatically dispense respective doses of the labeled radiopharmaceutical agents to the container.

For some applications, the patient information includes an identifier of an imaging 20 protocol assigned to the patient for performance using the dose, and wherein the control unit is configured to drive the communication element to transmit the imaging protocol identifier to the container data carrier.

For some applications, the control unit is configured to drive the communication element to transmit to the container data carrier at least one of: a time of dispensing of the 25 labeled radiopharmaceutical agent to the container, and information regarding a radioactivity of the dose at the time of dispensing.

In an embodiment, the apparatus comprises:

a mother vial that contains the labeled radiopharmaceutical agent prior to dispensing thereof; and

30 a computer-communicatable mother vial data carrier associated with the mother vial, which mother vial data carrier contains the radiopharmaceutical information, wherein the control unit is configured to receive the radiopharmaceutical

information from the mother vial data carrier.

For some applications, the radiopharmaceutical information comprises the imaging protocol information. For some applications, the imaging protocol information comprises SPECT imaging protocol information, which may comprise at least one kinetic 5 parameter of the at least one labeled radiopharmaceutical agent.

In an embodiment, the radiopharmaceutical information comprises the authenticatable information regarding the commercial license. For some applications, the information regarding the commercial license comprises information regarding the commercial license for use of a SPECT imaging protocol with the at least one labeled 10 radiopharmaceutical agent. For some applications, the control unit is configured to authenticate the authenticatable license information, and to drive the robot to automatically dispense the dose only upon authentication.

There is still further provided, in accordance with an embodiment of the present invention, apparatus for use with a container, the apparatus comprising:

15 a mother vial having a volume of at least 10 ml, which contains at least 5 ml of a non-diluted labeled radiopharmaceutical agent, and at least 5 ml of saline solution; and
an automated radiopharmaceutical dispensing system, configured to contain the mother vial, and to dispense at least one dose from the mother vial to the container.

There is additionally provided, in accordance with an embodiment of the present 20 invention, a method comprising:

placing at least one labeled radiopharmaceutical agent in a container;
associating a portable computer-communicatable data carrier with the container;
and

writing, to the data carrier, imaging protocol information for use with the at least 25 one labeled radiopharmaceutical agent.

There is yet additionally provided, in accordance with an embodiment of the present invention, a method comprising:

placing at least one labeled radiopharmaceutical agent in a container;
associating a computer-communicatable data carrier with the container; and
30 writing, to the data carrier, authenticatable information regarding a commercial license for use of SPECT imaging protocol information with the at least one labeled

radiopharmaceutical agent.

There is also provided, in accordance with an embodiment of the present invention, a method comprising:

- 5 providing a portable computer-communicatable data carrier; and
- writing, to the data carrier, authenticatable information regarding a commercial license for use of SPECT imaging protocol information.

There is further provided, in accordance with an embodiment of the present invention, a method comprising:

- 10 writing first and second identifier values to first and second computer-communicatable data carriers, respectively;
- detecting a correspondence between the first and second identifier values; and
- perform an imaging procedure on a patient responsively to the detecting.

There is still further provided, in accordance with an embodiment of the present invention, a method for use with at least one labeled radiopharmaceutical agent for 15 administration to a patient, the method comprising:

- placing at least one labeled radiopharmaceutical agent in a container;
- physically coupling a first computer-communicatable data carrier to the container;
- writing, to the first data carrier, radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent; and
- 20 writing, to a second portable computer-communicatable data carrier, patient information regarding the patient, and imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

There is additionally provided, in accordance with an embodiment of the present invention, a method comprising:

- 25 placing, in a container, at least one labeled radiopharmaceutical agent for administration to a patient;
- associating a computer-communicatable data carrier with the container;
- writing data to the data carrier regarding at least one of: the labeled radiopharmaceutical agent and the patient;
- 30 reading the data from the data carrier at a SPECT imaging system;
- utilizing the read data to customize at least one function of the system selected

from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

5 There is yet additionally provided, in accordance with an embodiment of the present invention, a method for use with a container containing at least one labeled radiopharmaceutical agent for administration to a patient, and data regarding at least one of: the labeled radiopharmaceutical agent and the patient, the method comprising:

reading the data at a SPECT imaging system; and

10 utilizing the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

15 There is also provided, in accordance with an embodiment of the present invention, a method for use with a container and a computer-communicatable container data carrier associated with the container, the method comprising:

20 receiving, by an automated radiopharmaceutical dispensing system, radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent, the radiopharmaceutical information selected from the group consisting of: imaging protocol information for use with the at least one labeled radiopharmaceutical agent, and authenticatable information regarding a commercial license for use of an imaging protocol with the at least one labeled radiopharmaceutical agent;

25 receiving, by the dispensing system, patient information regarding a patient; automatically robotically dispensing, by the dispensing system, a dose of the labeled radiopharmaceutical agent to the container; and

transmitting to the container data carrier, by the dispensing system, at least a portion of the radiopharmaceutical information and at least a portion of the patient information.

30 There is further provided, in accordance with an embodiment of the present invention, a method for automatically dispensing a labeled radiopharmaceutical agent to a

container, comprising:

- providing a mother vial having a volume of at least 10 ml;
- filling the mother vial with at least 5 ml of a non-diluted labeled radiopharmaceutical agent, and with at least 5 ml of saline solution;
- 5 placing the mother vial in an automated radiopharmaceutical dispensing system; and
- dispensing at least one dose from the mother vial to the container.

There is also provided, in accordance with an embodiment of the present invention, a method for setting a dose of a labeled radiopharmaceutical agent for use for 10 performing an imaging procedure on a patient for studying a physiological characteristic of the patient, the method including:

- selecting the radiopharmaceutical agent;
- receiving information regarding a medical parameter of the patient not directly related to the physiological characteristic of the patient; and
- 15 setting the dose at least in part responsively to the received information.

There is further provided, in accordance with an embodiment of the present invention, a substance associated with a time-dependent substance intake program generated by a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and 20 intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is still further provided, in accordance with an embodiment of the present invention, a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and 25 intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter, for indicating a time-dependent substance intake program.

There is yet further provided, in accordance with an embodiment of the present invention, a substance associated with a time-dependent substance intake program. 30 generated by a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and

intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is also provided, in accordance with an embodiment of the present invention, a time-dependent substance intake program generated by a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is further provided, in accordance with an embodiment of the present invention, a substance formulated in accordance with a time-dependent substance intake program generated by a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is still further provided, in accordance with an embodiment of the present invention, an apparatus, method, and/or functionality for generation of a machine readable multi-parameter human physiological profile including at least one of a kinetic and intra-body location dependent parameter, including providing a time-dependent substance intake program; a data acquisition system which acquires data from the patient passing through the intake program; and a computerized analysis using a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is yet further provided, in accordance with an embodiment of the present invention, an apparatus, method, and/or functionality for generation of a human physiological profile, including providing a substance intake program; a data acquisition system which acquires data from the patient passing through the intake program; and a computerized analysis using a substance profile, including at least one kinetic parameter.

There is also provided, in accordance with an embodiment of the present invention, an interactive pharmaceutical-containing, machine-readable information-bearing, customized medicine module suitable for use in computerized customized medicine, said customized medicine module including a computerized

customized medicine machine-interfaceable pharmaceutical-containing delivery module and a computerized individualized medicine machine-readable information-containing carrier containing at least data regarding said pharmaceutical which is required for use of said pharmaceutical in computerized customized medicine, said data being useful in 5 computerized customized medicine machine actuation of said pharmaceutical-containing delivery module.

There is additionally provided, in accordance with an embodiment of the present invention, a computerized customized medicine machine including:

- 10 a computerized patient imager;
- 10 a computerized pharmaceutical deliverer employing a pharmaceutical-containing, machine-readable information-bearing, customized medicine module; and
- 15 a customized medicine protocol controller including:
 - an interactive patient imager interface including patient information receiving functionality and patient imaging actuation functionality; and
 - 15 an interactive pharmaceutical deliverer interface including patient information receiving functionality and patient information-responsive pharmaceutical delivery actuation functionality.

There is also provided, in accordance with an embodiment of the present invention, an interactive pharmaceutical-containing, machine-readable authenticated, 20 authenticated customized medicine module suitable for use in computerized customized medicine, said customized medicine module including a computerized customized medicine machine-interfaceable pharmaceutical-containing module and a computerized individualized medicine machine-readable authentication-containing carrier containing at least authentication data regarding said pharmaceutical which is required for use of said 25 pharmaceutical in computerized customized medicine, said data being useful in said computerized customized medicine machine.

There is further provided, in accordance with an embodiment of the present invention, a computerized customized medicine preparation machine including:

- 30 a computerized patient information manager;
- 30 a computerized customized medicine pharmaceutical information manager;
- 30 a computerized authenticated customized medicine module authenticator; and

a computerized pharmaceutical-containing, machine-readable information-bearing, customized medicine module generator including:

5 a computerized generator protocol manager operative to receive patient information from said patient information manager, to receive authentication of an authenticated customized medicine module from said authenticator, to receive customized medicine pharmaceutical information relating to at least one pharmaceutical contained in said authenticated customized medicine module from said pharmaceutical information manager and to prepare customized medicine information to be included in said customized medicine module; and

10 a computerized pharmaceutical-containing, machine-readable information-bearing, customized medicine module preparer operative to associate said customized medicine information prepared by said protocol manager in an authenticatable machine readable form with a quantity of said pharmaceutical contained in said authenticated customized medicine module, thereby providing a

15 pharmaceutical-containing, machine-readable information-bearing, customized medicine module.

There is still further provided, in accordance with an embodiment of the present invention, an interactive pharmaceutical-containing, machine-readable information-bearing, individualized medicine module suitable for use in computerized individualized medicine, said individualized medicine module including a computerized individualized medicine machine actuatable pharmaceutical-containing delivery module and a computerized individualized medicine machine-readable information-containing carrier containing at least data regarding said pharmaceutical which is required for use of said pharmaceutical in computerized individualized medicine, said data being useful in computerized individualized medicine machine actuation of said pharmaceutical-containing delivery module.

For some applications, said data is in an encrypted format, readable by said computerized individualized medicine machine upon receipt of a predetermined authentication.

30 There is also provided, in accordance with an embodiment of the present invention, a computerized individualized medicine machine including:
a computerized patient imager;

a computerized pharmaceutical deliverer employing a pharmaceutical-containing, machine-readable information-bearing, individualized medicine module; and
an individualized medicine protocol controller including:

5 an interactive patient imager interface including patient image receiving functionality and patient imaging actuation functionality; and

an interactive pharmaceutical deliverer interface including patient image receiving functionality and patient image-responsive pharmaceutical delivery actuation functionality.

There is further provided, in accordance with an embodiment of the present
10 invention, use of a high definition, high sensitivity camera for determination of an optimal parameter for a labeled radiopharmaceutical agent, the optimal parameter selected from the group consisting of: optimal dose, optimal mode of administration, optimal mode of acquisition of data with respect to the labeled radiopharmaceutical agent, optimal mode of data processing with respect to the labeled radiopharmaceutical agent, and optimal mode
15 of presentation of information acquired with respect to the labeled radiopharmaceutical agent.

There is still further provided, in accordance with an embodiment of the present invention, a labeled radiopharmaceutical agent that is manufactured or designed or indicated for use with or sold with any one of the above techniques.

20 The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of an end-to-end automated system for medical imaging, in accordance with an embodiment of the present invention;

25 Fig. 2 is a flow chart showing an end-to-end method for medical imaging, in accordance with an embodiment of the present invention;

Fig. 3 is a schematic illustration of a patient-specific data carrier, in accordance with an embodiment of the present invention;

30 Fig. 4 is a schematic illustration of a patient management system, in accordance with an embodiment of the present invention;

Fig. 5 is a schematic illustration of a radiopharmaceutical dose calculation system, in accordance with an embodiment of the present invention;

Figs. 6A-E are tables showing exemplary preconfigured SPECT protocols and parameters thereof, in accordance with respective embodiments of the present invention;

5 Fig. 7 is a schematic illustration of a mother vial and attached data carrier, in accordance with an embodiment of the present invention;

Fig. 8 is a schematic illustration of a data carrier coupled to a radiopharmaceutical agent container, in accordance with an embodiment of the present invention;

10 Figs. 9A-H are schematic illustrations of respective embodiments of a radiopharmaceutical agent container and data carrier coupled thereto, in accordance with respective embodiments of the present invention;

Fig. 10 is a schematic illustration of an administration system, in accordance with an embodiment of the present invention;

15 Fig. 11 is a schematic illustration of an imaging system, in accordance with an embodiment of the present invention;

Fig. 12 is a schematic illustration of an automated radiopharmaceutical dispensing system, in accordance with an embodiment of the present invention;

Figs. 13A-C are schematic illustrations of a system for carrying out a data transfer process, in accordance with an embodiment of the present invention;

20 Fig. 14 is a schematic illustration of a radioisotope automatic elution system, in accordance with an embodiment of the present invention;

Fig. 15 is a schematic illustration of a mother vial preparation system, in accordance with an embodiment of the present invention;

25 Figs. 16A-B are illustrations of color spectra and a color-coded signature, respectively, in accordance with an embodiment of the present invention;

Fig. 17 is a schematic illustration of a computer-readable medium, a portion of which is shaped so as to define a physical key, in accordance with an embodiment of the present invention; and

Fig. 18 is a graph showing particle energy vs. photon count at a detector of a

camera, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Fig. 1 is a schematic illustration of an end-to-end automated system 10 for medical imaging, in accordance with an embodiment of the present invention. System 10 comprises a plurality of integrated elements that are configured to electronically exchange information among one another. The elements include an automated radiopharmaceutical dispensing system 20, a portable information-bearing radiopharmaceutical agent container 22, a portable patient-specific data carrier 24, an automated administration system 26, and an automated imaging system 28. The systems perform their respective automated functions at least in part responsively to the exchanged information. The elements typically authenticate one another via the exchanged information, in order to ensure that only authorized elements participate in the system, and that only authorized and appropriate functions are performed. Each of the elements is described in detail hereinbelow.

15 *End-to-end imaging method*

Fig. 2 is a flow chart showing an end-to-end method for medical imaging, in accordance with an embodiment of the present invention. At a radiopharmaceutical provisioning step 100, a manufacturer 102 (Fig. 1) or distributor provides a mother vial 104 (Fig. 1) containing an unlabeled radiopharmaceutical agent, and information associated with the radiopharmaceutical agent. Such an unlabeled radiopharmaceutical agent typically comprises a pharmaceutical substance, for example an antibody such as Capromab Pendetide marketed by Cytogen Corp. under the name ProstaScint and used in the detection of prostate cancer metastases, or sestamibi used in cardiac perfusion studies and marketed under the name of Cardiolite by Bristol Meyers Squibb Corporation, an ion, or another biological metabolized substance, or a substance which is not metabolized but nevertheless undergoes an interaction with the body. The information is stored in a mother vial data carrier 106 associated with mother vial 104, as described hereinbelow with reference to Fig. 7. For some applications, data carrier 106 is physically coupled to mother vial 104, while for other applications the data carrier is provided as a separate element associated with the mother vial. As described hereinbelow with reference to Fig. 7, the information stored in data carrier 106 typically includes information regarding the

radiopharmaceutical agent, such as the formulation, pharmacologic kinetic parameters, radioactivity information, and/or protocol information.

At a labeling step 110, the unlabeled radiopharmaceutical agent is labeled with an appropriate radioisotope, to produce a labeled radiopharmaceutical agent. Such labeling 5 is typically performed using conventional methods, including mixing the agent with a solution containing the radioisotope, heating the mixture, and performing quality testing on the labeled radiopharmaceutical agent. For some applications, step 110 is performed using conventional radiopharmacy labeling techniques, while for other applications system 10 comprises a mother vial preparation system 700, which automatically performs 10 all or a portion of the labeling, as described hereinbelow with reference to Fig. 15. The radioisotopes are provided by a radioisotope supplier 111, such as a conventional radiopharmacy or an automatic elution system 600, described hereinbelow with reference to Fig. 14. Data carrier 106 is typically updated with radioactivity-related information, including the time of labeling, the radioactivity of the radioisotope at the time of labeling, 15 and the volume of the labeled radiopharmaceutical agent, as described hereinbelow with reference to Fig. 7.

For some applications, the only active constituent of the labeled radiopharmaceutical agent is the radioisotope; in other words, the radioisotope is not bound to a biologically active substance. For example, the labeled radiopharmaceutical 20 agent may consist essentially of thallium (as well as pH-balancing constituents, salt ions, and preservatives). As used in the present application, including in the claims, a "labeled radiopharmaceutical agent" means either: (a) an agent comprising a diagnostic radioisotope, such as thallium, or (b) an agent comprising a radioisotope bound to a biologically active substance, such as an antibody, a pharmaceutical compound, an ion, or 25 another biological metabolized substance, or a substance which is not metabolized but nevertheless undergoes an interaction with the body.

At a patient registration and imaging protocol assignment step 112, a healthcare worker 206 uses a patient management system 160 to register a patient into system 10, and to assign appropriate administration and imaging protocols for the patient, as 30 described in detail hereinbelow with reference to Fig. 4. At an information transfer step 114, patient management system 160 assigns a portable patient-specific data carrier 24 to the patient, and transmits information to data carrier 24, including at least a patient

identifier (typically, the patient's identification code and/or name), and the assigned administration and imaging protocols. Additional patient data parameters recorded may include physiological data such as girth, height and weight. The patient management system additionally transmits an order for one or more patient-specific doses of the 5 appropriate labeled radiopharmaceutical agent(s) to dispensing system 20 or a conventional radiopharmacy.

At a dose dispensing step 116, dispensing system 20 dispenses the ordered customized dose of the labeled radiopharmaceutical agent from mother vial 104, as described in detail hereinbelow with reference to Fig. 12. Prior to dispensing the dose, 10 dispensing system 20 typically authenticates the mother vial using information stored in mother vial data carrier 106. For some applications, dispensing system 20 verifies the authenticity of a commercial license contained in data carrier 106. Typically, all or a portion of the information used for such verification is encrypted, and dispensing system 20 decrypts the information during the verification procedure. Alternatively or 15 additionally, dispensing system 20 accesses, over a network, information stored at a remote site, and utilizes the information for such verification. The dispensing system dispenses the dose based on patient-specific prescription information, radiopharmaceutical agent-related information stored in data carrier 106, and/or patient-specific information provided by an element of system 10. Such patient-specific 20 information may include, for example, age, weight, Body Mass Index (BMI), body dimensions, metabolic rate, hemodynamic state, and/or kinetic parameters of the labeled radiopharmaceutical agent as determined during previous imaging procedures performed on the patient. For some applications, dosage information is provided directly or indirectly by patient management system 160 and/or a radiopharmaceutical dose 25 calculation system 152, which are described hereinbelow with reference to Figs. 4 and 5, respectively.

At an information transfer step 118, dispensing system 20 transfers patient-specific information and radiopharmaceutical-related information to a data carrier 120 physically coupled to container 22, as described hereinbelow with reference to Figs. 30 9A-H and 10. "Physically coupled," as used in the present application, including the claims, includes both direct and indirect physical coupling. For example, data carrier 120 may be indirectly physically coupled to container 22 via shielding of container 22, or shielding of a cylinder in which container 22 is stored during transport and handling

thereof. The patient-specific information includes the patient's identification code and/or name, and the assigned administration and imaging protocols. The radiopharmaceutical-related information typically includes: (a) all or a portion of the information provided by the manufacturer in data carrier 106, such as described hereinbelow with reference to Fig. 7, e.g., intended use, formulation, pharmacologic kinetic parameters, and protocol information; (b) information regarding the radioactivity and volume of the dose; and (c) time of dispensing, as described in detail hereinbelow with reference to Fig. 8. In addition, the dispensing system typically prints and attaches a conventional information label to container 22, such as in order to comply with regulatory labeling requirements. For applications in which the labeled radiopharmaceutical agent(s) is dispensed using conventional radiopharmacy techniques, dispensing system 20, or another element of system 10, such as dose calculation system 152, typically transfers the radiopharmaceutical-related information to data carrier 120. Alternatively, all or a portion of the information is transferred directly from mother vial data carrier 106 to container 15 data carrier 120.

At an administration step 122, administration system 26 receives radiopharmaceutical agent container 22, and administers the labeled radiopharmaceutical agent contained therein to the appropriate patient. As described hereinbelow with reference to Fig. 10, for some applications, administration system 26 comprises an automated administration device, which is configured to administer the labeled radiopharmaceutical agent, while for other applications, a healthcare worker manually administers the agent upon receiving a signal to do so from system 26. Prior to administration, system 26 authenticates container 22 and verifies the identity of the patient, using information provided by patient-specific data carrier 24 and container data carrier 120, and, optionally, another element of system 10, such as a physician station 115. Typically, all or a portion of the information used for such verification is encrypted, and administration system 26 decrypts the information during the verification procedure. Alternatively or additionally, administration system 26 accesses, over a network, information stored at a remote site, and utilizes the information for such verification. 30 Administration system 26 verifies that the patient identification codes contained in patient-specific data carrier 24 and container data carrier 120 match one another, and, typically, verifies that the administration and/or imaging protocols contained in the data carriers match one another. Typically, at least a portion of the information stored in data

carrier 120 of container 22 is transferred to data carrier 24, either directly, via administration system 26, or via a communication element. For some applications, system 26 generates a signal for a healthcare worker confirming that a proper match has been made between agent container 22 and the patient. The system also typically verifies 5 that the current time is the proper administration time, as per the administration protocol, and that container 22 contains the proper dose, as per the selected protocol. Optionally, system 26 is configured to administer the labeled radiopharmaceutical agent only if such matches are confirmed by the system. For some applications, administration system 26 verifies the authenticity of a commercial license contained in data carrier 120, and 10 performs the administration only upon verification of the authenticity.

For some applications, administration system 26 customizes the administration of the labeled radiopharmaceutical agent using information provided by data carrier 24, data carrier 120, physician station 115, and/or patient management system 160. For example, system 26 may customize a time-dependent administration profile of the labeled 15 radiopharmaceutical agent, such as a rate of administration. Alternatively or additionally, system 26 may administer less than the entire dose of the labeled radiopharmaceutical agent, e.g., based on feedback from imaging system 28 during an imaging procedure.

For some applications, such as dynamic studies, administration system 26 administers the labeled radiopharmaceutical agent during an imaging procedure 20 performed by imaging system 28. For these applications, the administration system is in communication with the imaging system during the administration, in order to assure information regarding time-dependent administration is accurately communicated between the administration system and the imaging system. For some applications, imaging system 28 reads information from patient-specific data carrier 24, and transmits 25 at least a portion of the information to administration system 26, thereby obviating the need for the administration system to directly read such information from the data carrier. For some applications, imaging system 28 triggers the commencement of administration. (It is to be understood that although the imaging system triggers administration of the agent, for some applications the agent is not administered until a healthcare worker 30 provides a final authorization to do so, such as to comply with regulatory safety requirements.) For some applications, the labeled radiopharmaceutical agent(s) is administered in a closed loop with an imaging procedure performed by imaging system 28; administration system 28 modifies one or more parameters of the administration in

real time based on feedback received from imaging system 28, and/or based on real-time measurements of physiological parameters of the patient (e.g., systemic blood concentrations) during the imaging procedure. For some protocols, the administration system administers a preliminary bolus injection, and, based on feedback from imaging system 28 and/or on physiological parameters of the patient, configures one or more parameters of a subsequent administration of the same or a different labeled radiopharmaceutical agent.

At an information transfer step 123, before, during and/or after administration of the labeled radiopharmaceutical agent, system 26 electronically updates patient-specific data carrier 24 with details of the administration, such as:

- an identification code of container 22 and/or an administration device;
- an identification code of the patient to which the labeled radiopharmaceutical agent was dispensed, which should match the patient code already stored in data carrier 24;
- the administered labeled radiopharmaceutical agent;
- the volume of the labeled radiopharmaceutical agent administered;
- the time of administration;
- the time profile of administration;
- the radioactivity of the labeled radiopharmaceutical agent at the time of administration;
- the radioactivity of the labeled radiopharmaceutical agent when dispensed to container 22;
- the time of measurement of the radioactivity when dispensed to container 22; and/or
- at least a portion of the radiopharmaceutical information provided by data carrier 106 of mother vial 104.

For some applications, data carrier 120 of container 22 communicates administration information to patient-specific data carrier 24, either directly or via administration system 26. For some applications, system 26 provides similar updates to

other elements of system 10, such as patient management system 160, management control component 150, physician station 115, and/or imaging system 28. Alternatively or additionally, a healthcare worker manually updates one or more of the data carrier and/or system elements. Typically, for safety purposes, after administration system 26 5 has read all necessary information from data carrier 120, administration system 26 permanently disables data carrier 120 of container 22, in order to ensure that the data carrier is not accidentally reused for another patient.

Reference is still made to Fig. 2. After or during administration of the labeled radiopharmaceutical agent, imaging system 28 performs an imaging procedure on the 10 patient, at an imaging step 124. Imaging system 28 is described hereinbelow with reference to Fig. 11. Prior to performing the imaging procedure, system 28 verifies one or more of the following:

- the identity of the patient, using information provided by patient-specific data carrier 24;
- the authenticity of patient-specific data carrier 24, typically using information provided by the data carrier itself, a coded signature 256, as described hereinbelow in the section entitled "Signature," and/or a key 852, as described hereinbelow with reference to Fig. 17;
- that patient-specific data carrier 24 has been brought within a certain 20 distance of imaging system 28, e.g., within about 30 cm;
- the identity of the manufacturer or distributor of the radiopharmaceutical agent, using information stored in data carrier 120;
- that a selected camera of imaging system 28, imaging protocol, and patient 25 identification code, as provided to imaging system 28 by one or more elements of system 10, match those stored in patient-specific data carrier 24;
- the authenticity of a commercial license contained in patient-specific data carrier 24. For some applications, system 28 verifies that the license has not been previously used, for example by verifying that a registration code 30 associated with the license has not been previously received by system 28 and/or system 10; and/or

- that administration system 26 used (or is about to use, for procedures in which administration occurs during imaging) the correct container 22 and associated data carrier 120 for the prescribed imaging procedure, and administered (or is about to administer) the appropriate dose of the labeled radiopharmaceutical agent(s) at time(s) appropriate for performance of the imaging procedure.

5 Typically, all or a portion of the information used for such verification is encrypted, and imaging system 28 decrypts the information during the verification procedure. Alternatively or additionally, imaging system 28 accesses, over a network, 10 information stored at a remote site, and utilizes the information for such verification.

For some applications, system 28 generates a signal for a healthcare worker confirming that a proper match has been made between the patient and one or more of the components described above. Optionally, system 28 is configured to perform the imaging procedure only if such a match is confirmed by the system.

15 Typically, system 28 customizes the imaging procedure using information provided by administration system 26, data carrier 24, and/or physician station 115. Such information typically includes information regarding the time of labeled radiopharmaceutical administration, the labeled radiopharmaceutical agent (e.g., radioactive strength, time of preparation, and/or kinetic parameters), patient-specific 20 physiological information, and/or imaging protocol information. Parameters of the imaging procedure that are typically customized include, but are not limited to: total acquisition time; detector motions, such as detector angular and translational motions, detector step size (i.e., the density of the step size, typically expressed in degrees), and detector dwell time at each view; type of study, such as standard, active vision (as 25 described in the above-mentioned International Application PCT/IL2005/001173), or gated; definition of the region of interest (ROI), for example, based on the size of the heart; and/or attenuation correction parameters, which are typically based on physiological parameters such as body mass, BMI, and girth.

At an image reconstruction step 126, imaging system 28 uses the acquired imaging 30 data for image reconstruction. For some applications, system 28 customizes the image reconstruction procedure using information provided by administration system 26, data carrier 24, and/or physician station 115.

Imaging system 28 analyzes the reconstructed image, at an analysis step 128. For some applications, system 28 customizes the analysis procedure using information provided by administration system 26, data carrier 24, and/or physician station 115.

The imaging system, or a separate diagnostic system of system 10, assists with 5 developing a diagnosis based on the analysis, at a diagnosis step 130. Typically, system 28 customizes the diagnostic procedure using information provided by administration system 26, data carrier 24, and/or physician station 115. For some applications, authentication is performed to verify that the imaging was performed as intended. Reconstruction and analysis are preferably based on lookup tables and expert system 10 rules, for example, as provided by the radiopharmaceutical manufacturer, and may be patient customized, taking into account known patient physiology and/or suspected disease. Alternatively or additionally, the lookup tables and/or expert system diagnostic rules are configured to provide such customization. For some applications, customization and/or diagnostic techniques are performed that are described in the above-mentioned 15 International Application PCT/IL2005/001173.

The diagnosis and/or the results of the imaging procedure are typically transmitted to physician station 115, for use by an attending healthcare worker 206. Alternatively or additionally, the diagnosis and/or the results of the imaging procedure are transmitted to a database 132 (Fig. 1). The accumulated results of a number of such imaging procedures 20 for a large population are analyzed in order to develop, optimize, update, or otherwise re-evaluate imaging protocols, and update appropriate lookup tables and/or expert system rules for the use of the radiopharmaceutical agent. For example, the database may contain quantitative data regarding absolute blood flow measurements from healthy patients and patients with varying level of diseases. For some applications, such data is used to obtain 25 disease-specific tissue signatures by performing quantitative analysis of normal and diseased tissue. Alternatively or additionally, the information in database 132 is used for: (a) comparing the results of an imaging procedure (images, and/or quantitative information and/or analyses) with historical results of the patient, in order to classify disease state and/or (b) comparing the results of an imaging procedure with similar results 30 from a patient population, in order to classify disease state.

Typically, physician station 115 comprises one or more standard personal computers or servers with appropriate memory, communication interfaces and software

for carrying out the functions prescribed by relevant embodiments of the present invention. This software may be downloaded to the physician station in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM.

5 During or after steps 124 through 128, imaging system 28 updates the data stored in patient-specific data carrier 24 and/or other elements of system 10, such as patient information system 160, and/or physician station 115, to reflect details of the imaging procedure performed. In addition, for some applications, imaging system 28 transfers data to the specific camera used for the procedure, such as patient details, 10 radiopharmaceutical information, and/or administration information, which information is received from data carrier 24, or from other elements of system 10.

The patient-specific data carrier

Reference is made to Fig. 3, which is a schematic illustration of patient-specific data carrier 24, in accordance with an embodiment of the present invention. Data carrier 15 24 is configured to be held or worn by the patient, and, for some applications, comprises a coupling mechanism configured to be coupled to the patient, which coupling mechanism, comprises, for example, a bracelet, watch, or necklace (Fig. 3A shows the data carrier integrated into a watch or bracelet 170). Data carrier 24 is computer-communicatable, and typically comprises an RFID tag, smart card, disk-on-key (e.g., a USB key), or other 20 electronic memory, as described below. Data carrier 24 is configured to hold information regarding the patient and a selected imaging procedure, as described immediately hereinbelow with reference to Fig. 4.

One or more communication elements 240 are provided for reading data from and transmitting data to data carrier 24 e.g., using a proprietary or standard wireless protocol, 25 e.g., Bluetooth, WiFi, W-LAN, or IEEE 802.11. Alternatively, the communication element is brought into physical contact with data carrier 24, and reads and/or writes the information using an electrical contact, or other coupling technique, such as inductive coupling. Respective communication elements 240 are typically in data communication with patient management system 160, physician station 115, dispensing system 20, 30 administration system 26, and/or imaging system 28. For some applications, communication elements 240 comprise one or more coils for transmitting and receiving electromagnetic radiation. Typically, the communication elements are configured to have

a short effective transmission range, e.g., no more than between about 20 and 40 cm, such as about 30 cm. Such a short range reduces the likelihood of accidental communication with a data carrier other than the intended data carrier.

For some applications, a portion of the patient information stored in the data carrier is also printed in human- and/or machine-readable form on the data carrier. For example, a name 172 and identification code 174 of the patient, and/or a barcode 176 may be printed on the data carrier.

Data carrier 24 comprises circuitry 178, which comprises memory and logic. For some applications, data carrier 24 is passive, in which case it is configured to receive energy from communication element 240. For other applications, data carrier 24 comprises a power source (not shown). For some applications in which the data carrier comprises a power source, the data carrier comprises a communication element for communicating and/or energizing another electronic apparatus. Alternatively or additionally, the data carrier comprises a communication element configured for wireless communication.

For some applications, data carrier 24 further comprises a user output 180 for outputting information to the patient or healthcare workers. For example, output 180 may comprise a display screen, light, and/or sound generator, which circuitry 178 drives to communicate information, such as when communications have been established with other elements of system 10, e.g., data carrier 120, administration system 26, imaging system 28, and/or patient management system 160. For some applications, circuitry 178 is configured to additionally function as an alarm clock; for example, the circuitry may drive display 180 to alert the patient prior to a scheduled administration or imaging procedure.

Typically, for safety purposes, upon completion of all the imaging procedures associated with a given patient-specific data carrier 24, system 10 permanently disables the data carrier, in order to ensure that the data carrier is not accidentally reused for another patient.

The patient management system

Reference is made to Fig. 4, which is a schematic illustration of patient management system 160, in accordance with an embodiment of the present invention.

Patient management system 160 manages patient-related administrative and medical information, and typically comprises at least one workstation 200 in communication with one or more servers 202. Typically, workstation 200 and servers 202 comprise standard personal computers and/or computer servers with appropriate memory, communication 5 interfaces and software for carrying out the functions prescribed by relevant embodiments of the present invention. This software may be downloaded to the workstation and servers in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM.

System 160 performs the following functions:

- 10 • receives and registers new patients into system 10, typically into management and control component 150 thereof;
- assigns patient identification codes;
- assigns, issues, and transfers information to patient-specific data carriers 24;
- 15 • receives and tracks patient prescriptions for radiopharmaceuticals, and communicates the prescriptions to other elements of system 10, such as dispensing system 20, administration system 26, and/or management and control component 150; and/or
- suggests and assigns imaging protocols based on the patient's imaging 20 needs and patient-specific information.

During reception of a new patient 204, healthcare worker 206 manually enters patient information into workstation 200. Alternatively or additionally, all or a portion of the patient information is provided electronically by another healthcare system or electronic information source. System 160 typically verifies the healthcare worker's 25 identity and access privileges by interrogating a computer-communicatable identity tag 208 held by the worker, and/or by checking the validity of a password entered into workstation 200 by the healthcare worker.

The patient information provided to system 160 typically includes:

- 30 • the patient's general details, such as name, age, gender, address, telephone number, profession, attending and/or treating physician, health insurance plan, and next of

kin;

- the patient's medical profile, such as medical condition, medical history, family medical history, BMI, weight, allergies, sensitivity to one or more chemical compounds, metabolic rate, and other physiological conditions;
- 5 ● medications prescribed to the patient;
- the patient's imaging history; and/or
- information regarding the desired imaging, including reason for imaging, type of imaging, body structure or organ to be imaged, and known or suspected pathology.

In an embodiment of the present invention, upon entry of such patient information
10 into patient management system 160, the system automatically suggests one or more imaging protocols that may be appropriate for the patient's imaging needs and medical condition. When making such suggestion, the system takes into consideration, in addition to the information regarding the desired imaging, such factors as the patient's general details, medical profile, imaging history, and guidelines for medication interactions. The
15 system typically selects the suggested protocol(s) from a database of preconfigured protocols, which is described hereinbelow with reference to Figs. 6A-E. Healthcare worker 206 selects one of the suggested protocols, or selects another non-suggested protocol directly from the protocol database.

For some applications, the system suggests one or more customizations of the
20 selected protocol, as described hereinbelow with reference to Figs. 6A-E, which the healthcare worker may accept, decline, or modify, in whole or in part. These suggested customizations are typically based on (a) physiological parameters of the patient, such as age, weight, BMI, metabolic rate, and/or hemodynamic state, and/or kinetic parameters of the radiopharmaceutical agent as determined during previous imaging procedures
25 performed on the patient, and/or (b) a medical profile group to which the patient is assigned, such as high, normal, or low BMI, or high BMI - diabetic, or high BMI - normal metabolic rate. (For some applications, such profile groups are stored in a database of management and control component 150.) Alternatively or additionally, the healthcare worker may customize the protocol manually.

30 Upon selection and customization of the protocol, patient management system 160 schedules, typically automatically:

- a specific imaging system 28 capable of performing the selected imaging procedure;
- a date and time for performing the imaging procedure; and
- a date(s) and time(s) for administration of labeled radiopharmaceutical agent(s).

5 Patient management system 160 transmits the entered and generated patient-specific information, including the selected protocol, to the patient's patient-specific data carrier 24. The transmitted patient-specific information typically includes:

- 10 • the patient's identification code and name;
- an identifier of the selected imaging protocol(s), such as a name and/or an identification code thereof, and/or additional imaging protocol information, such as described hereinbelow with reference to Figs. 6A-E;
- an identifier of the selected administration protocol(s), such as a name and/or an identification code thereof;
- 15 • the scheduled imaging system 28;
- the scheduled imaging date and time;
- the scheduled administration date(s) and time(s);
- the patient's personal details;
- 20 • the patient's medical profile; and/or
- the patient's imaging history.

25 The patient management system transmits an order for one or more patient-specific doses of the appropriate labeled radiopharmaceutical agent(s) to dispensing system 20, such as via management and control component 150. Typically, the patient management system additionally transmits at least a portion of the entered and generated patient-specific information to one or more of: (a) management and control component 150, (b) dose calculation system 152, (c) administration system 26, and/or (d) imaging system 28. Typically, a different subset of the information is transmitted to each of these entities.

As described hereinabove with reference to Fig. 3, for some applications, a portion of the patient information stored in data carrier 24 is also printed in human- and/or machine-readable form on the data carrier. For example, a name 172 and identification code 174 of the patient, and/or a barcode 176 may be printed on the data carrier. For such 5 applications, system 160 comprises a printer 210, which is configured to print the information directly on data carrier 24, or to print the information on an adhesive label, which healthcare worker 206 attaches to data carrier 24. For some applications, printer 210 comprises communication element 240, and the printer is configured to both print the information on the data carrier and transmit the information to the data carrier, typically 10 generally at the same time.

In an embodiment of the present invention, system 10 comprises at least one web server, which is configured to accept orders for an imaging procedure over an intranet or the Internet, placed by a physician or other healthcare worker. Such orders can typically be modified up until a deadline, such as midnight before the day of the scheduled imaging 15 procedure.

The management and control component

Reference is again made to Fig. 1. In an embodiment of the present invention, system 10 comprises management and control component 150, which coordinates a portion of the interaction and communication among the elements of system 10. The 20 remainder of the interaction and communication occurs directly between the elements of the system, and/or via other elements of the system. For some applications, component 150 issues a password and/or computer-communicatable identity tags 208 to healthcare workers 206 authorized to interact with one or more elements of system 10. For example, tag 208 may comprise an RFID tag, smart card, disk-on-key (e.g., a USB key), minidisk, 25 or other electronic memory, or a machine-readable code, e.g., a barcode. As appropriate, healthcare workers 206 may be assigned various permission levels, such as permission to view or modify particular system and/or patient data.

Typically, management and control component 150 comprises one or more standard personal computers or servers with appropriate memory, communication 30 interfaces and software for carrying out the functions prescribed by relevant embodiments of the present invention. This software may be downloaded to the management and control component in electronic form over a network, for example, or it may alternatively

be supplied on tangible media, such as CD-ROM.

The dose calculation system

Reference is made to Fig. 5, which is a schematic illustration of radiopharmaceutical dose calculation system 152, in accordance with an embodiment of 5 the present invention. The dose calculation system manages and tracks, typically automatically, radiopharmaceutical inventory, ordering, dose dispensing, and disposal. Typically, the dose calculation system comprises one or more standard personal computers or servers with appropriate memory, communication interfaces and software for carrying out the functions prescribed by relevant embodiments of the present 10 invention. This software may be downloaded to the dose calculation system in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM. The dose calculation system receives information from dispensing system 20 regarding doses drawn from the inventory.

Dose calculation system 152 typically comprises:

- 15 • an ordering sub-system 154, which orders radiopharmaceutical products from radiopharmaceutical manufacturers, distributors, and/or radiopharmacies, typically automatically, such as when the dose calculation system identifies that inventories of a given radiopharmaceutical are lower than needed;
- 20 • a receipt and verification sub-system 155, which manages the receipt and registration of radiopharmaceutical products. The receipt and verification sub-system checks the received products against orders placed by the ordering sub-system, and typically performs license management. When a received mother vial 104 includes a mother vial data carrier 106, the sub-system reads information contained in the data carrier to verify that the order has been accurately fulfilled, and, typically, verifies the 25 authenticity of the mother vial;
- 30 • a dose calculation sub-system 156, which calculates customized doses of labeled radiopharmaceutical agents for patients based on patient-specific information, protocol information, and/or prescription information, and communicates the customized doses to patient management system 160

and/or dispensing system 20; and/or

- a waste-disposal sub-system 157, which tracks radioactive waste disposal by system 10, such as disposal of radioactive materials contained in waste container 512, described hereinbelow with reference to Fig. 12. For some applications, sub-system 157 additionally tracks radioactive waste disposal of materials in the clinical environment not associated with system 10.

Ordering sub-system 154 and waste-disposal sub-system 157 typically operate in accordance with per country requirements for radiopharmaceutical use. A reporting sub-system reports to relevant nuclear regulatory commissions as required, based on information obtained from the other sub-systems.

In an embodiment of the present invention, dose calculation sub-system 156 designs a cocktail of labeled radiopharmaceutical agents or a series of labeled radiopharmaceutical agents to carry out the desired imaging. When designing such a cocktail or series, the sub-system considers constraints imposed by the physical properties of the agents and by the patient history, and other requirements, such as safety and efficacy requirements. The sub-system determines an appropriate dose for the specific patient having particular physiological parameters (e.g., weight, BMI, and age), and determines the times at which multiple agents are to be administered to the patient in order to achieve optimal imaging.

For some applications, sub-system 156 determines that a plurality of labeled radiopharmaceutical agents are to be administered together and thus must be combined in a single preparation, i.e., a cocktail. For other applications, the sub-system determines that a plurality of labeled radiopharmaceutical agents are to be administered separately at different times and thus must be contained in separate containers 22. As appropriate, sub-system 156 takes into consideration differing half-lives of the plurality of labeled radiopharmaceutical agents, in conjunction with the prescribed time of the imaging procedure. For example, a simultaneous imaging protocol is provided for assessing cardiac perfusion using a cocktail comprising Tc-99m sestamibi injected at rest, and thallium-201 injected at stress, wherein the desired activities at imaging time of the Tc-99m sestamibi and the thallium are 6 mCi and 4 mCi, respectively. When calculating the necessary activity of the dispensed dose, sub-system 156 accounts for the respective half-lives of Tc-99m (6 hours) and thallium-201 (64 hours) in view of the planned time

interval between the dispensing time and administration time. For example, if dispensing is performed 24 hours before administration, sub-system 156 calculates the activities of the Tc-99m and thallium-201 at the time of dispensing to be 96 mCi and 5.5 mCi, respectively.

5 *Protocol information*

Reference is made to Figs. 6A-E, which is a table showing exemplary preconfigured SPECT protocols and parameters thereof, in accordance with respective embodiments of the present invention. These protocols are appropriate, for example, for use with the SPECT imaging methods and apparatus described hereinbelow with reference to Fig. 11, and/or in the co-assigned patent applications and/or patent application publications incorporated herein by reference hereinabove. For some applications, the techniques described herein utilize additional protocols described in above-mentioned International Application PCT/IL2005/001173, International Application PCT/IL2005/001215, filed November 16, 2005, above-mentioned US 15 Provisional Patent Application 60/628,105, above-mentioned US Provisional Patent Application 60/675,892, or in one or more of the other co-assigned patent applications and/or patent application publications incorporated herein by reference. Alternatively or additionally, the techniques described herein utilize protocols for non-SPECT imaging modalities, such as PET or CT, or other imaging modalities known in the art. The 20 preconfigured protocols are stored in a database, which is typically used by patient management system 160 for suggesting protocols and/or by dose calculation sub-system 156, as described hereinabove with reference to Figs. 4 and 5, respectively.

For each of the exemplary protocols shown in Fig. 6A, the table indicates general parameters for a rest phase and a stress phase of the protocol. For example, for the "single isotope / low dose / fast imaging" protocol, the table shows that the radiopharmaceutical (RP) for the rest phase of the protocol is less than 0.3 mCi of Thallium, that the waiting time after injection of the radiopharmaceutical is 2 minutes, and that the image acquisition duration is 15 minutes. Parameters for the stress phase are similarly indicated, with the addition of the type of stress (exercise, e.g., treadmill or bicycle, or pharmaceutical, e.g., 25 adenosine). The "thallium stress perfusion" and "simultaneous dual isotope stress perfusion" protocols are optionally dynamic.

For each of the exemplary protocols shown in Figs. 6B-E, the table indicates

administration parameters, detector parameters, scanning parameters, and analysis parameters for the protocol. For example, for Protocol A of Figs. 6B-C ("Cardiac mapping"), the table indicates:

- the labeled radiopharmaceutical agent is Tc-99-sestamibi (MIBI);
- 5 • the protocol is a fast protocol, with image acquisition completed prior to substantial uptake of the agent by the liver;
- the injection is by a single bolus;
- 10 • image acquisition begins either about 2 minutes after injection, or during or immediately after administration, for applications in which the administration is performed while the patient is already placed at camera 452 (Fig. 11);
- the detected photon energy is 140 KeV with an energy resolution of 15%, i.e., the total range of energy levels detected by the detectors 454 of camera 452 (Fig. 11) is set to be 15% of the emitted energy level of the labeled radiopharmaceutical agent (140 Kev). Typically, this range is not 15 centered around the emitted energy level, but instead is shifted towards lower energy levels;
- 20 • the total scan time is 120 seconds;
- four detectors 454 of camera 452 are assigned as outer (distal) detectors, and six detectors 454 are assigned as inner (proximal) detectors, as described hereinbelow with reference to Fig. 11;
- each of the inner detectors has an angular range of between 90 and 120 degrees, and each of the outer detectors has an angular range of between 40 and 60 degrees;
- 25 • the total number of angular orientations assumed by the detectors in aggregate is 1200, i.e., 10 detectors times 120 orientations each;
- each angular step of the inner detectors is one degree, and each angular step of the outer detectors is 0.3 to 0.5 degrees (corresponding to the range of 40 to 60 degrees described above);
- 30 • the dwell time at each step is one second, for both the inner and outer detectors;

- the imaging procedure is gated using 16 to 32 frames;
- the analyses to be performed include intensity image and ejection fraction.

For some applications, the protocol information includes additional information not shown in Figs. 6B-E, such as:

5 • additional scanning parameters, such as whether the detectors perform multiple scans (in all the protocols shown in the table, the detectors typically perform a single scan); and

10 • additional analysis parameters, such as:

- saturation handling (in the first cardiac mapping protocol shown in the table, no saturation handling is performed, while in the second cardiac mapping protocol shown in the table, the analysis is configured to dismiss saturated pixels);
- whether the analysis handles scatter from multiple sources (in the protocols shown in the table, the analysis does not handle scatter from multiple sources);
- reconstruction resolution (in all of the protocols shown in the table, the image reconstruction resolution is 2.5 mm in the z-direction, and 5 mm in the x- and y-directions); and
- parameters that provide the diagnosis system (e.g., expert system) with information regarding how to interpret the results of the imaging study, such as kinetic parameters, predefined pathological values, or patient-specific physiological parameters (e.g., BMI, age, or a group to which the patient is assigned).

15 20 25

Reference is made to Protocol E of Figs. 6B-C. In this cardiac mapping protocol, simultaneous image acquisition is performed using, typically using full conventional doses of both thallium and MIBI-Tc. The detected photon energy of the thallium is 167 KeV, rather than the 72 KeV that is conventionally detected during nuclear imaging procedures. Unlike conventional SPECT cameras, the camera described hereinbelow with reference to Fig. 11 is sufficiently sensitive to detect a clinically-relevant count of the relatively low percentage (8%) of photons emitted at the 167 KeV energy level.

(Detection of 72 KeV energy is generally not practical when a conventional dose of MIBI-Tc is used, because the scatter from the 140 KeV energy level of MIBI-Tc masks the 72 KeV photons emitted by the thallium.)

Reference is made to Protocol I of Figs. 6D-E. In this cardiac dynamic mapping 5 protocol, image acquisition typically begins prior to administration of the radiopharmaceutical agent, such as at one minute prior to administration, as shown in the table. This allows the imaging system to complete one full scan of the region of interest prior to administration of the radiopharmaceutical agent, in order to ensure that the imaging system is able to acquire photons of radiation beginning immediately after the 10 radiopharmaceutical agent is administered.

Typically, a selected preconfigured protocol is customized based on physiological parameters of the specific patient, and/or a medical profile group of the patient, as described hereinabove with reference to Fig. 4. Such customization typically includes customization of the radiopharmaceutical agent, administration parameters, and/or 15 imaging parameters.

For some applications, one or more of the following parameters of the radiopharmaceutical agent are customized:

- the dose, or for multiple radiopharmaceutical agents, the respective doses;
- the radioactivity;
- 20 • for cocktails, the ratio of the different radiopharmaceutical agents; and/or
- the volume of the dose, or for multiple radiopharmaceutical agents, the volumes of the respective doses.

For some applications, one or more of the following parameters of the administration are customized:

- 25 • the dose administered, or for multiple radiopharmaceutical agents, the respective doses per administration;
- the type of administration, e.g., a single bolus, a plurality of boluses (e.g., two boluses), pulsatile administration, or constant drip administration;
- 30 • the labeled radiopharmaceutical agent for each administration, whether a single agent or a cocktail of agents;

- the time of the administration with respect to the time of imaging;
- the timings of multiple administrations with respect to each other and with respect to other activities, such as rest or stress (physical or pharmacological);
- 5 ● the administration device, e.g., a syringe, a dual-needle syringe, a pump, or an IV line; and/or
- the mode of administration, e.g., manual, automatic, or computer driven.

For some applications, one or more of the following parameters of the imaging procedure are customized. For some applications, such parameters are separately 10 specified for individual components of camera 452 of imaging system 28, or groups of components, such as for individual detectors 454 or groups of detectors of camera 452, described hereinbelow with reference to Fig. 11.

- total acquisition time, and/or acquisition time for a plurality of phases of acquisition;
- 15 ● detector scanning plan, including detector motions, such as detector angular and translational motions, detector step size (i.e., the density of the step size, typically expressed in degrees), number of detectors utilized for image acquisition, and detector dwell time at each view;
- detector sensitivity;
- 20 ● detection energy resolution;
- detector calibration plan;
- definition of the region of interest (ROI);
- gating parameters;
- energy bands, i.e., a plurality of non-overlapping energy windows;
- 25 ● collimator positioning, shape, structure, and orientation;
- multiple/interlaced scans;
- zooming parameters;
- uniformity/non-uniformity of scan;

- Compton scatter map calculation and correction parameters;
- optimal energy window;
- optimal energy resolution, i.e., the range of energy level windows for which detection is enabled; and/or
- 5 • adaptivity of scan pattern to acquired counts, e.g., active vision parameters (as described in the above-mentioned International Application PCT/IL2005/001173).

In an embodiment of the present invention, system 10 uses high definition protocols in conjunction with SPECT imaging techniques to enable personalized functional imaging at higher speeds and resolutions than can be achieved using conventional radiopharmaceutical protocols and imaging technology, using imaging techniques described herein and/or incorporated herein by reference. Alternatively or additionally, the system uses low dose protocols that enable personalized functional imaging at higher resolutions but with substantially lower doses than possible using 15 conventional methods.

In an embodiment of the present invention, system 10 uses a protocol pursuant to which a patient undergoes a rest thallium (Tl-201-thallous chloride) and stress Tc-99-sestamibi (MIBI) study having a total study duration of between about 60 and about 90 minutes, and a total image acquisition duration of between about 0.5 and about 6 20 minutes, e.g., about four minutes. For example, pursuant to the protocol:

- about 3 mCi of thallium may be administered to the patient as a bolus IV injection,
- the patient may rest for between about 10 and about 15 minutes,
- an image acquisition having a duration of about two minutes may be 25 performed,
- the patient may be physically stressed,
- about 20-30 mCi of Tc-99-sestamibi may be administered as a bolus IV injection, and
- a second image acquisition having a duration of about two minutes may be 30 performed.

Such dual-isotope imaging is generally useful for assessing myocardial perfusion of patients with suspected ischemic syndromes and a variety of other conditions. Alternatively, in an embodiment, the rest phase is performed using an approximately 8 to 10 mCi dose of Tc-99m-sestamibi, in which case image acquisition typically commences 5 about 30 minutes after injection of the sestamibi. Further alternatively, in an embodiment, image acquisition for the rest phase is performed about two minutes after injection of the thallium, the stress is pharmacological (e.g., using adenosine), and image acquisition for the stress phase is performed essentially immediately after injection of the sestamibi. Still further alternatively, in an embodiment, the rest phase is performed using 10 Tc-99m-sestamibi, and image acquisition commences essentially immediately upon injection of a dose of about 8 to 10 mCi.

In accordance with respective embodiments of the present invention, dual-radiopharmaceutical protocols include the administration and simultaneous imaging of the following combinations of labeled radiopharmaceutical agents. Typically, the 15 labeled radiopharmaceutical agents are administered as a mixture (i.e., a cocktail) before or during a simultaneous imaging procedure; alternatively, the labeled radiopharmaceutical agents are administered separately before or during a simultaneous imaging procedure.

- (a) I-123 BMIPP, a fatty acid imaging agent that has been available in 20 Japan for many years, and is currently in Phase III clinical trials in the United States, and (b) a myocardial perfusion agent (e.g., Tc-99m sestamibi, Tc-99m tetrofosmin, or Tl-201-thallous chloride), for simultaneously studying myocardial perfusion and fatty acid metabolism;
- (a) Tl-201-thallous chloride and (b) Tc-99m pertechnetate, for 25 differentiating an organ from its anatomical surroundings, such as differentiating parathyroid glands from the thyroid gland;
- (a) In-111 DTPA, and (b) Tc-99m-MAG3, for differentiating pathological processes in a given organ, such as performing differential diagnosis of a hypo-perfused kidney, e.g., to study true glomerular filtration rate and 30 tubular secretion simultaneously;
- a cocktail of labeled radiopharmaceutical agents, for studying cancer, including simultaneous diagnosis, prediction of therapy response, and

monitoring of therapy, such as simultaneously identifying a tumor, and characterizing tumor perfusion and metabolic activity, e.g., in order to provide a disease signature; and

- the combinations shown in the following table.

TABLE 1

First radiopharmaceutical	First application	Second radiopharmaceutical	Second application
201Tl	Myocardial perfusion	Tc-99m-teboroxime	Myocardial perfusion
		Tc-99m-sestamibi	
		Tc-99m-tetrofosmin	
201Tl	Myocardial perfusion	Tc-99m-PYP	Infarct Imaging
201Tl	Myocardial perfusion	Tc-99m-Annexin	Apoptosis
201Tl	Myocardial perfusion	123I-BMIPP	Hypoxia
Tc-99m-teboroxime	Myocardial perfusion	111In-Annexin	Apoptosis
Tc-99m-teboroxime	Myocardial perfusion	123I-Fatty acid	Metabolism
111In-WBC	Infection	Tc-99m-SC	Bone Marrow
111In-DTPA	Kidney (GFR)	Tc-99m-MAG3	Kidney (tubular secretion)
Tc-99m-RBC	Blood pool	111In-Prostascint	Prostate cancer
Tc-99m-HMPAO	Cerebral blood flow	123I-IBZM	Dopamine D2 receptors

In an embodiment of the present invention, system 10 uses protocols for studying the kinetics of thallium. For some applications, such protocols provide dynamic information regarding myocardial function, such as blood flow, rate of thallium uptake, thallium accumulation/redistribution, thallium metabolism, and/or thallium and/or metabolite secretion and/or wash-out (active or passive). Kinetic perfusion

radiopharmaceutical modeling provides absolute myocardial perfusion measurements, coronary flow reserve, and parametric representation of cellular function.

In accordance with respective embodiments of the present invention, thallium protocols include:

- 5 • protocols using a conventional dose of thallium, with a substantially reduced SPECT image acquisition duration, e.g., less than about 6 minutes, such as less than about 2 minutes, e.g., about 0.5 minutes. By way of comparison, conventional thallium SPECT imaging procedures generally have image acquisition durations of between about 10 and about 10 minutes. For some applications, the thallium protocol is customized for a specific patient, as described hereinabove;
- 10 • protocols using a conventional dose of thallium and a conventional image acquisition duration, with a substantially increased image resolution. For some applications, acquired photon counts are at least 5 times greater than 15 those acquired using conventional SPECT techniques, e.g., at least 10 times greater, resulting in an image with substantially higher resolution; and
- 20 • dynamic protocols for myocardial perfusion studies that provide absolute quantitative measurements. For example, images of the heart may be reconstructed from list mode data, with a temporal resolution of 5-10 seconds. This temporal resolution is typically appropriate for the measurement of the kinetics of uptake and wash-out of thallium from the myocardium, as well as those of an input bolus as it passes through the left ventricle. Such data enables the measurement of absolute myocardial 25 blood flow at rest and during peak stress.

In an embodiment of the present invention, system 10 uses protocols for cardiac stress testing studies, using, for example, Tc99m-sestamibi, Tc-99m tetrofosmin, or thallium. Such protocols differentiate between healthy cardiac tissue and scarred or poorly perfused cardiac tissue. Perfusion defects that appear after exercise or 30 pharmacologic stress suggest either vascular occlusion or myocardial infarction. For some applications, such studies are performed gated to the patient's ECG, in order to study cardiac wall motion. Wall motion studies allow calculation of key cardiac function

parameters, such as ejection fraction and estimated cardiac output.

In accordance with respective embodiments of the present invention, cardiac stress testing protocols, which use, for example, Tc99m-sestamibi, Tc-99m tetrofosmin, or thallium, include:

5 • protocols using a conventional dose, with a substantially reduced SPECT image acquisition duration, e.g., less than about 6 minutes, such as less than about 2 minutes, e.g., about 0.5 minutes. By way of comparison, conventional cardiac stress testing SPECT imaging procedures generally have image acquisition durations of between about 10 and about 20

10 minutes. For some applications, the protocol is customized for a specific patient, as described hereinabove. For some applications, such as when the protocol uses Tc99m-sestamibi, image acquisition is performed immediately following administration of the labeled radiopharmaceutical agent, before the agent reaches the liver, thereby reducing interference by

15 the liver on the resulting images.

• protocols using a dose of the labeled radiopharmaceutical agent that is substantially lower than conventional SPECT protocols using the agent. For example, the dose may be between about 50% and about 90% lower than a conventional dose, e.g., about 50% lower than a conventional dose.

20 By using the image acquisition techniques described herein and/or incorporated herein by reference, even at such reduced doses, acquired photon counts are typically at least 5 times greater than those acquired using conventional SPECT techniques at conventional SPECT doses, e.g., at 10 times greater, and image acquisition duration is typically about 50% less than conventional durations, e.g., about 80% less (such as four minutes instead of 20 minutes). Alternatively, the dose may be reduced by about 90%, and the image acquisition duration is approximately the same as conventional image acquisition durations.

25

In an embodiment of the present invention, system 10 uses Tc-99m teboroxime for 30 performing a SPECT myocardial perfusion study. This radiopharmaceutical is extracted by the myocardium in proportion to myocardial blood flow throughout the entire range of achievable flow rates. When conventional imaging techniques are used, the wash-out rate

of Tc-99m teboroxime from cardiac tissue is so rapid that there is inadequate time for imaging, because the radiopharmaceutical rapidly and avidly accumulates in the liver, which emits gamma rays that blind the imaging of the heart. By using the imaging techniques described herein and/or incorporated herein by reference, sufficient photon 5 counts are obtained in an image acquisition period of no more than approximately two minutes, immediately following administration. The use of such a short period enables the completion of image acquisition prior to substantial uptake of the radiopharmaceutical by the liver, thereby enabling the effective clinical use of Tc-99m teboroxime for cardiac imaging.

10 In an embodiment of the present invention, a dynamic multiple isotope combination protocol is provided for studying different pathological processes of the same organ, such as studying acute myocardial ischemia. In accordance with this protocol, the following labeled radiopharmaceutical agents are administered as bolus IV injections:

15 (a) an approximately 2 mCi dose of I-123-BMIPP, followed by a wait of about 48 hours;

(b) an approximately 1 mCi dose of Tl-201-thallous chloride; and

(c) either (i) an approximately 10 mCi dose of Tc-99m-sestamibi or (ii) an approximately 10 mCi dose of Tc-99m-teboroxime.

20 Agents (b) and (c) are administered as a cocktail, or as separate injections at approximately the same time. Simultaneous image acquisition of all three radiopharmaceutical agents is performed during or soon after administration of agents (b) and (c), typically using an up to about 30 minute acquisition time, such as between about 5 and about 15 minutes, which is faster than that of standard imaging protocols.

25 Typically, camera 452 of imaging system 28, described hereinbelow with reference to Fig. 11, performs image acquisition using an energy window of between about 2% and about 10% of the emitted energy levels of the radiopharmaceutical agents. Typically, detectors 454 of camera 452 sweep the region of interest once every approximately 10 to approximately 15 seconds. The I-123-BMIPP identifies the ischemic/infarcted area of the 30 myocardium, while the other radiopharmaceutical agents identify the perfused area of the myocardium. Simultaneous imaging provides more accurate identification of myocardial perfusion pathologies than is generally possible using conventional imaging techniques

and protocols.

In an embodiment of the present invention, system 10 uses one or more of the protocols described in the above-mentioned US provisional application filed on even date herewith, entitled, "Imaging protocols."

5 In some embodiments of the present invention, the protocols described herein (including those shown in Figs. 6A-E), and in the co-assigned patent applications incorporated herein by reference, are performed using values that vary from those provided in the protocols by +/- 20%, e.g., +/- 5%, +/- 10%, or +/- 15%. Furthermore, in some embodiments, the protocols are performed with a range of doses from 50%, 75%,
10 90%, or 100% of the dosage value given for the respective protocol, up to 10 times the dosage value given for the respective protocol (such as up to 2, 4, 6, or 8 times the given dosage value). For example, a dose shown as 3 mCi for a given protocol may, in some embodiments, have a range of 1.5 mCi to 30 mCi, or from 2.7 mCi to 6 mCi. Similarly, in some embodiments, the protocols are performed with a range of acquisition durations
15 (total scan times) from 50%, 75%, 90%, or 100% of the duration value given for the respective protocol, up to 5 times the duration value given for the respective protocol, such as up to 1.5, 2, 3, or 4 times the given duration value. Other protocol values, such as waiting times, energy windows/resolution, angular range, angular step, and dwell time, may also have a range from 50%, 75%, 90%, or 100% of the value given for the
20 respective protocol, up to 5 times the value given for the respective protocol, such up to 1.5, 2, 3, or 4 times the given value.

In respective embodiments of the present invention, all of the protocols described herein and/or in the co-assigned patent applications incorporated herein by reference are enabled to generate clinically-valuable images. A "clinically-valuable image" is an image
25 of an intra-body region of interest (ROI) containing the labeled radiopharmaceutical agent(s), which image fulfills one or more of the following criteria:

- the image is generated according to a protocol, including at the radiopharmaceutical dose specified by the protocol, using a high-definition SPECT camera, for example, camera 452 of imaging system 28, described hereinbelow with reference to Fig. 11, which camera, during the imaging of the ROI, is capable of acquiring at least one of 5000 photons emitted from the ROI during the image acquisition procedure, such as at least one

of 4000, 3000, 2500, 2000, 1500, 1200, 1000, 800, 600, 400, 200, 100, or 50 photons emitted from the ROI. In one particular embodiment, the camera is capable of acquiring at least one of 2000 photons emitted from the ROI during the image acquisition procedure;

5 • the image is generated according to a protocol, including at the radiopharmaceutical dose and image acquisition duration specified by the protocol, using a high-definition SPECT camera, for example, camera 452, which, during the imaging of the ROI, is capable of acquiring at least 200,000 photons, such as at least 500,000, 1,000,000, 2,000,000, 10 3,000,000, 4,000,000, 5,000,000, 8,000,000, or 10,000,000 photons, emitted from a portion of the ROI having a volume of no more than 500 cc, such as a volume of no more than 500 cc, 400 cc, 300 cc, 200 cc, 150 cc, 100cc, or 50 cc. In one particular embodiment, the camera is capable of acquiring at least 1,000,000 photons emitted from a volume of the ROI 15 having a volume of no more than 200 cc;

15 • the image has a resolution of at least 7x7x7 mm, such as at least 6x6x6 mm, 5x5x5 mm, 4x4x4 mm, 4x3x3 mm, or 3x3x3 mm, in at least 50% of the reconstructed volume, wherein the labeled radiopharmaceutical agent as distributed within the ROI has a range of emission-intensities R (which 20 is measured as emitted photons / unit time / volume), and wherein at least 50% of the voxels of the reconstructed three-dimensional emission-intensity image of the ROI have inaccuracies of less than 30% of range R, such as less than 25%, 20%, 15%, 10%, 5%, 2%, 1%, or 0.5% of range R. For example, the agent may emit over a range from 0 25 photons/second/cc to 10^5 photons/second/cc, such that the range R is 10^5 photons/second/cc, and at least 50% of the voxels of the reconstructed three-dimensional intensity image of the ROI have inaccuracies of less than 15% of range R, i.e., less than 1.5×10^4 photons/second/cc. For some applications, the study produce a parametric 30 image related to a physiological process occurring in each voxel. In one particular embodiment, the image has a resolution of at least 5x5x5 mm, and at least 50% of the voxel have inaccuracies of less than 15% of range R;

- the image is generated according to a protocol, including at the radiopharmaceutical dose and image acquisition duration specified by the protocol, the image has a resolution of at least 7x7x7 mm, such as at least 6x6x6 mm, 5x5x5 mm, 4x4x4 mm, 4x3x3 mm, or 3x3x3 mm, wherein the labeled radiopharmaceutical agent has a range of intensities R (photons / unit time / volume), and wherein at least 50% of the voxels of the reconstructed three-dimensional intensity image of the ROI have inaccuracies of less than 30% of range R, such as less than 25%, 20%, 15%, 10%, 5%, 2%, 1%, or 0.5% of range R. For some applications, the study produce a parametric image related to a physiological process occurring in each voxel; and/or
- the image has a resolution of at least 20x20x20 mm, such as at least 15x15x15 mm, 10x10x10 mm, 7x7x7 mm, 5x5x5 mm, 4x4x4 mm, 4x3x3 mm, or 3x3x3 mm, wherein values of parameters of a physiological process modeled by a parametric representation have a range of physiological parameter values R, and wherein at least 50% of the voxels of the reconstructed parametric three-dimensional image have inaccuracies less than 100% of range R, such as less than 70%, 50%, 40%, 30%, 25%, 20%, 15%, 10%, 5%, 2%, 1%, or 0.5% of range R. For example, the physiological process may include blood flow, the values of the parameters of the physiological process may have a range from 0 to 100 cc / minute, such that the range R is 100 cc / minute, and at least 50% of the voxels of the reconstructed parametric three-dimensional image have inaccuracies less than 25% of range R, i.e., less than 25 cc / minute. In one particular embodiment, the image has a resolution of at least 5x5x5 mm, and at least 50% of the voxels have inaccuracies of less than 25% of range R.

The mother vial

Reference is made to Fig. 7, which is a schematic illustration of mother vial 104 and attached data carrier 106, in accordance with an embodiment of the present invention. Data carrier 106 is computer-communicatable, and typically comprises an RFID tag, smart card, disk-on-key (e.g., a USB key), compact disc, minidisk, disposable

computer-readable medium, or other electronic memory, or a machine-readable code, e.g., a barcode. Mother vial 104 is shown contained within shielding 272, to which data carrier 106 is attached. Alternatively, the data carrier is attached directly to the mother vial, or otherwise associated with the mother vial, such as by being stored in proximity to the 5 mother vial, e.g., in a tray that also contains the mother vial.

Data carrier 106 typically contains at least some of the following information:

- a coded signature 256, for authenticating mother vial 104;
- radiopharmaceutical information, a portion of which is typically supplied by the manufacturer, and a portion of which is typically generated by dispensing system 20 in conjunction with dispensing the radiopharmaceutical agent(s). For some applications, a portion of the information is generated by mother vial preparation system 700, described hereinbelow with reference to Fig. 15, in conjunction with preparing the radiopharmaceutical. The information includes, for example:
 - the name of and/or information regarding the manufacturer;
 - the indicated use(s) (e.g., "Formulation for Cardiac Dynamic Studies");
 - the pre-labeled composition;
 - the time of preparation of the labeled radiopharmaceutical agent(s);
 - the radioactivity at the time of preparation;
 - the total solution volume;
 - the pre-labeled-composition expiration date;
 - the appropriate labeling isotope(s);
 - the decay scheme(s) of the appropriate labeling isotope(s);
 - the radiopharmaceutical biodistribution as a function of time;
 - the radiopharmaceutical clearance rate;
 - the percent clearance by the liver;
 - the percent clearance by the kidneys;
 - the breakdown rate;

- the liver uptake as a function of time; and/or
- radiopharmaceutical kinetic parameters, such as described hereinbelow, which parameters may be stored in one or more lookup tables;

5 • administration protocol information, such as described hereinbelow;

 • image acquisition protocol information, such as described hereinbelow;

 • image reconstruction protocol information, such as described hereinbelow;

 • image analysis protocol information, such as described hereinbelow;

 • expert system protocol information, such as described hereinbelow;

10 • radiolabeling information, which, for some applications, is generated by mother vial preparation system 700, described hereinbelow with reference to Fig. 15. Such information includes, for example:

- the labeling radioisotope(s), e.g., Tc-99m;
- time of labeling;

15 - activity of the radioisotope(s) per volume at the time of labeling;

 - total solution volume in the mother vial; and/or

 - ratio of radioisotopes (e.g., Tc-99m to Tc-99) at the time of labeling.

If the labeled radiopharmaceutical agent stored in the mother vial is radiolabeled by mother vial preparation system 700, as described hereinbelow with reference to Fig. 20 15, the labeling information is provided by the mother vial preparation system. Otherwise, the labeling information is provided by the pharmacist and/or conventional labeling system that radiolabels the unlabeled radiopharmaceutical agent.

The radiopharmaceutical kinetic parameters are used by imaging system 28 for performing dynamic imaging studies, for example as described in the above-mentioned 25 International Patent Application PCT/IL2005/001173, and/or in the above-mentioned US provisional application filed on even date herewith, entitled, "Imaging protocols". For some applications, respective sets of these parameters are provided for:

- different patient populations, such as a healthy population and populations which suffer from various pathologies;

- different organs and/or tissue types, for example, brain tissue, cardiac tissue, liver tissue, and tumor tissue;
- different pathologies;
- different patient physiologies;
- 5 • different organs, according to the physiology of the specific patient;
- different patient groups, as expected according to the physiology of the specific patient;
- different pathologies, as expected according to the physiology of the specific patient;
- 10 • different organs, as measured for the specific patient;
- different patient groups, as measured for the specific patient; and/or
- different pathologies, as measured for the specific patient.

Such kinetic parameters may include, for example:

- volume of blood in a voxel;
- 15 • density of blood in a tissue within a voxel;
- labeled radiopharmaceutical agent concentration in the blood within a voxel;
- labeled radiopharmaceutical agent concentration in a tissue within a voxel;
- total labeled radiopharmaceutical agent concentration in a voxel;
- 20 • labeled radiopharmaceutical agent concentration in the systemic blood circulation;
- linearity with blood flow;
- receptor binding for molecular radiotracers;
- labeled radiopharmaceutical accumulation/redistribution in tissue;
- 25 • labeled radiopharmaceutical metabolic rate;
- diffusion coefficient from the blood to the tissue (i.e., rate of wash-out,

passive or active);

- diffusion coefficient from the tissue to the blood (i.e., rate of uptake, passive or active); and/or
- accumulation rate in a tissue within a voxel.

5 The administration protocol information is used by administration system 26 to set parameters of administration of the labeled radiopharmaceutical agent(s) contained in container 22. This protocol information may include, for example:

- the dose administered, or for multiple radiopharmaceutical agents, the respective doses per administration;
- the type of administration, e.g., a single bolus, a plurality of boluses (e.g., two boluses), pulsatile administration, or constant drip administration;
- the labeled radiopharmaceutical agent for each administration, whether a single agent or a cocktail of agents;
- the time of the administration with respect to the time of imaging;
- the timings of multiple administrations with respect to each other and with respect to other activities, such as rest or stress (physical or pharmacological);
- the administration device, e.g., a syringe, a dual-needle syringe, a pump, or an IV line;
- the mode of administration, e.g., manual, automatic, or computer driven; and/or
- an algorithm for customizing the administration based on physiological parameters of the specific patient.

25 The image acquisition protocol information is used by imaging system 28 to set parameters of the image acquisition process. For some applications, such parameters are separately specified for individual components of camera 452 of imaging system 28, or groups of components, such as for individual detectors 454 or groups of detectors. Such acquisition protocol information may include, for example:

- the name(s) and/or identification code(s) of one or more protocols for

which the radiopharmaceutical agent contained in mother vial 104 is suitable;

- total acquisition time, and/or acquisition time for a plurality of phases of acquisition;
- 5 • detector scanning plan, including detector motions, such as detector angular and translational motions, detector step size (typically expressed in degrees), and detector dwell time at each view;
- detector sensitivity;
- detector energy resolution;
- 10 • detector calibration plan;
- definition of the region of interest (ROI);
- gating parameters;
- energy bands, i.e., a plurality of non-overlapping energy windows;
- collimator positioning, shape, structure, and orientation;
- 15 • multiple/interlaced scans;
- zooming parameters;
- uniformity/non-uniformity of scan;
- Compton scatter map calculation and correction parameters;
- optimal energy window;
- 20 • optimal energy resolution, i.e., the range of energy window levels detected; and/or
- adaptivity of scan pattern to acquired counts, e.g., active vision parameters (as described in the above-mentioned International Application PCT/IL2005/001173).

25 For some applications, the optimal energy window is set at least in part responsively to the BMI of the patient. For example, the width of the energy window (i.e., the energy resolution) may be inversely related to the BMI, because the tissue of patients with higher BMIs tends to create more scatter. To compensate for narrower

energy windows, a longer acquisition time and/or a higher dose of radiopharmaceutical agent is typically used. For some applications, the protocol information includes a look-up table of BMIs and associated energy windows. For some applications, the energy window is non-symmetrical around a peak of the energy curve.

5 The image reconstruction protocol information is used by imaging system 28 to set parameters of the image reconstruction process. Such parameters may include, for example:

- calibration parameters;
- timing of acquisition;
- 10 • reconstruction parameters and algorithms;
- priors, i.e., mathematical constants signifying pre-imaging phase knowledge about system behavior;
- multi-resolution reconstruction parameters;
- non-uniform reconstruction grid;
- 15 • filters;
- noise modeling and handling;
- mode selection;
- information derived during image acquisition and/or gating;
- protocols for handling interfering organs;
- 20 • protocols describing the precise procedure to be followed in radiopharmaceutical administration, time management, patient activity status, imaging process, and other parameters that can affect imaging results;
- optimization parameters per dose and/or cocktail of doses; and/or
- 25 • attenuation correction parameters, which are typically based on physiological parameters such as body mass, BMI, and girth.

For some applications, imaging system 28 uses one or more of these parameters to perform the image reconstruction process using techniques described in one or more of

the co-assigned patent applications incorporated herein by reference.

The image analysis protocol information includes analysis algorithms and/or parameters of the image analysis process, which are used by imaging system 28 for performing diagnostic analysis of the reconstructed image. For some applications, such 5 analysis includes tracer kinetics analysis. Such parameters may include, for example:

- information for selection of a model of tracer kinetics;
- information for selection of one or more time scales for tracer kinetics;
- tracer parameters;
- information for analysis of multiple time points;
- 10 • information for analysis regarding the clinical meaning of radiation distribution within the patient's body for the purpose of making a clinical diagnosis regarding the patient's health state;
- information for identifying the signatures of multiple labeled radiopharmaceutical agents; and/or
- 15 • optimization parameters per dose and/or cocktail of doses.

The expert system protocol information, such as expert system rules, is used by imaging system 28 to set parameters of the expert system used for assisting with diagnosis. For some applications, the expert system is implemented using techniques described in the above-mentioned International Application PCT/IL2005/001173, or in 20 one or more of the other co-assigned patent applications incorporated by reference. Such parameters may include, for example:

- classification of the patient into a patient population;
- multi-parameter vectors of radiopharmaceutical kinetic parameters for different patient populations, such as a healthy population and populations 25 which suffer from various pathologies, and for different tissue types, for example, brain tissue, cardiac tissue, liver tissue, or tumor tissue;
- patient history;
- multi-dimensional thresholds for defining healthy-disease state;
- disease signature classifications per pathology and/or organ (typically per

patient population); and/or

- optimization parameters per dose and/or cocktail of doses.

The portable information-bearing radiopharmaceutical agent container

Fig. 8 is a schematic illustration of data carrier 120, in accordance with an embodiment of the present invention. As mentioned above, data carrier 120 is physically coupled to radiopharmaceutical agent container 22. Data carrier 120 is computer-communicatable, and typically comprises an RFID tag, smart card, disk-on-key (e.g., a USB key), compact disc, minidisk, disposable computer-readable medium, or other electronic memory, or a machine-readable code, e.g., a barcode. One or more communication elements 240 are provided for reading data from and transmitting data to data carrier 24. Respective communication elements 240 are typically in data communication with dispensing system 20 and administration system 26. For some applications, communication elements 240 comprise one or more coils for transmitting and receiving electromagnetic radiation. Typically, the communication elements are configured to have a short effective transmission range, e.g., no more than between about 20 and 40 cm, such as about 30 cm. Such a short range reduces the likelihood of accidental communication with a data carrier other than the intended data carrier.

Data carrier 120 comprises circuitry 250, which comprises memory and logic. For some applications, data carrier 120 is passive, in which case it is configured to receive energy from communication element 240. For other applications, data carrier 120 comprises a power source (not shown). For some applications in which the data carrier comprises a power source, the data carrier comprises a communication element for communicating and/or energizing another electronic apparatus. Alternatively or additionally, the data carrier comprises a communication element 252 configured for wireless communication. For some applications, data carrier 24 further comprises a user output 254 for outputting information to the patient or healthcare workers. For example, output 254 may comprise a display screen, light, and/or sound generator, which the circuitry drives to communicate information, such as when communications have been established with other elements of system 10, e.g., data carrier 120, administration system 26, or imaging system 28. For some applications, data carrier 120 further comprises coded signature 256, which is typically encrypted, color-coded, or both encrypted and color-coded, as described hereinbelow in the section entitled "Signature."

The information contained in data carrier 120 typically includes some or all of the following:

- an administration-device identification code;
- an identifier, such as an identification code and/or name, of the patient for 5 which the specific attached radiopharmaceutical agent container 22 is intended;
- the formulation of the labeled radiopharmaceutical agent(s) contained in attached container 22;
- the time of dispensing of the labeled radiopharmaceutical agent(s) to 10 container 22;
- activity of the labeled radiopharmaceutical agent(s), at the time of dispensing of the labeled radiopharmaceutical agent(s) to container 22;
- the assigned protocol(s) for use with the labeled radiopharmaceutical agent(s) contained in attached container 22;
- the intended time(s) and date(s) of administration of the labeled radiopharmaceutical agent(s) contained in container 22; 15
- the intended activity(ies) of the labeled radiopharmaceutical agent(s) at the time of administration thereof;
- the intended time profile of administration (single bolus, slow-drip 20 administration, or any other form of administration);
- the identification code of mother vial 104 from which the labeled radiopharmaceutical agent(s) contained in container 22 were dispensed; and/or
- at least a portion of the radiopharmaceutical information stored in data 25 carrier 106 of mother vial 104, as described hereinabove with reference to Fig. 7. This information is typically electronically transferred from data carrier 106 during dispensing of the labeled radiopharmaceutical agent(s) to container 22, as described hereinabove with reference to step 118 of Fig. 2 and hereinbelow with reference to Fig. 12.

As mentioned above, for some applications, all or a portion of the information contained in patient-specific data carrier 24 is alternatively or additionally stored in data carrier 120. Such information is described hereinabove with reference to Fig. 7. For some applications, a portion of the information stored in the data carrier is also printed in 5 human- and/or machine-readable form on the data carrier and/or on the container, for example as a barcode 260, as shown below in Figs. 9A-H.

In an embodiment of the present invention, radiopharmaceutical agent container 22 comprises all or a portion of a drug administration device, such as a syringe or an inhalation device, packaging for an oral dosage form, or radiopharmaceutical packaging.

10 Reference is made to Figs. 9A-H, which are schematic illustrations of respective embodiments of radiopharmaceutical agent container 22 and data carrier 120, in accordance with respective embodiments of the present invention. In all of these embodiments, data carrier 120 is physically coupled to agent container 22.

15 Fig. 9A is a schematic illustration of radiopharmaceutical agent container 22 comprising a manual syringe 270, in accordance with an embodiment of the present invention. Syringe 270 is protected by shielding 272, to which data carrier 120 is coupled. Alternatively, the data carrier is coupled directly to an exposed portion of the syringe, such as the end of the plunger of the syringe, as shown in the figure.

20 Fig. 9B is a schematic illustration of radiopharmaceutical agent container 22 comprising an automatic administration device 280, in accordance with an embodiment of the present invention. Device 280 comprises a chamber 282 for containing the labeled radiopharmaceutical agent(s), a needle 283, a controller 284, a drive 286, and a power source 288. For some applications, controller 284 is preprogrammed with administration 25 instructions, while for other applications, the controller is coupled to administration system 26 and receives an administration signal therefrom prior to administration, or in real time during administration. Administration device 280 typically includes an interlock 290 to prevent administration without verification, for example, of the patient's identity. For some applications, device 180 comprises a flow meter 292, which measures the 30 volume of labeled radiopharmaceutical agent administered. Controller 284 uses this flow information for regulating parameters of the administration, such as rate of administration and total amount of agent administered. Shielding 272 protects medical personnel from the radioactivity of the labeled radiopharmaceutical agent.

Fig. 9C is a schematic illustration of a multi-chamber embodiment of radiopharmaceutical agent container 22, in accordance with an embodiment of the present invention. In this embodiment, container 22 comprises a plurality of chambers in fluid isolation from one another, each of which chambers contains a labeled radiopharmaceutical agent. In the embodiment shown in Fig. 9C, the container comprises two such chambers, a first chamber 282A and a second chamber 282B. Alternatively, the container comprises more than two chambers (configuration not shown). For some multi-chamber applications, container 22 comprises automatic administration device 280, as shown in Fig. 9C, while for other multi-chamber applications, container 22 comprises a plurality of manual syringes 270, as described hereinabove with reference to Fig. 9A (multi-chamber configuration not shown). For some applications, a separate needle 283 is provided for each injection, while for other applications, container 22 is configured to utilize a single needle 283 for the plurality of injections. For example, needle 283 may be configured to slide along a needle mount 294, so as to service the plurality of chambers.

Fig. 9D is a schematic illustration of another configuration of radiopharmaceutical agent container 22, in accordance with an embodiment of the present invention. In this embodiment, container 22 comprises automatic administration device 280, as described hereinabove with reference to Fig. 9B, and controller 284 is configured to perform all or a portion of the functions of data carrier 120. For some applications, one or more of the elements of data carrier 120 are provided separately from the controller. For example, communication element 252 or user output 254 may be provided separately from the controller.

Figs. 9E-G are schematic illustrations of another configuration of radiopharmaceutical agent container 22 comprising manual syringe 270, in accordance with an embodiment of the present invention. In this embodiment, syringe 270 comprises a transmitter 296 fixed with respect to a plunger 298 of the syringe, and shielding 272 is configured so as to modulate effective transmission by transmitter 296. For example, shielding 272 may be shaped so as to define a longitudinal slot 300 along a portion of the shielding. This modulation serves to send, from syringe 270 to administration system 26 and/or imaging system 28, a signal indicative of a time of administration of the labeled radiopharmaceutical agent(s) contained in container 22. The techniques of this embodiment are typically useful when registration of the time of administration with imaging system 28 is important, such as for dynamic studies.

Figs. 9E-G respectively illustrate three steps for administration using these techniques. Fig. 9E shows a first step, during which transmitter 296 is exposed, and therefore effectively transmits a signal. Fig. 9F shows a second step, during which transmitter 296 is shielded by shield 272. Fig. 9G shows a third step, in which transmitter 296 is again exposed. This sequence of exposing, shielding, and again exposing the transmitter serves to signal that administration has occurred. The receiver of the signal (administration system 26 and/or imaging system 28) records the time that this signal is detected. For some applications, other techniques are used to automatically transmit an indication of when the labeled radiopharmaceutical agent(s) are administered. For example, a transmitter may be mounted on shield 272, and may send a signal when electrical contact is established between electrodes (not shown) on plunger 298 and shield 272 at the end of complete motion of the plunger into syringe 270.

Fig. 9H is a schematic illustration of a syringe adaptor 320, in accordance with an embodiment of the present invention. Adaptor 320 comprises shielding 272 and data carrier 120 coupled thereto. The adaptor is configured to placed on a standard administration device, such as a standard syringe. In an embodiment of the present invention, an adaptor similar to adaptor 320 is provided for use with other components of an end-to-end imaging system, such as Tc-99m vials, mother vials, dispensing tools, and dilution containers. Alternatively or additionally, data carrier 120 is configured to be couplable to such other components.

In an embodiment of the present invention, data carrier 120 is configured to be couplable to a standard administration device, such as a syringe. For example, the data carrier may be couplable to the barrel, plunger, or conventional shielding of a conventional syringe, or another syringe known in the art.

25 *The administration system*

Reference is made to Fig. 10, which is a schematic illustration of administration system 26, in accordance with an embodiment of the present invention. Administration system 26 comprises a control unit 350, at least one communication element 240, and, for some applications, an automated administration device 352. Typically, control unit 350 comprises a standard personal computer or server with appropriate memory, communication interfaces and software for carrying out the functions prescribed by relevant embodiments of the present invention. This software may be downloaded to the

control unit in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM. For some applications, administration system 26 comprises a single communication element 240 that communicates with both patient-specific data carrier 24 and data carrier 120 of container 22, while for other 5 applications the administration system comprises separate communication elements 240 for communicating with data carriers 120 and 24 respectively. For example, a communication element for communicating with data carrier 120 may be integrated into or coupled to automated administration device 352.

Upon authenticating container 22, verifying the identity of the patient, and 10 performing additional verifications, as described hereinabove with reference to step 122 of Fig. 2, control unit 350 generates an administration signal that triggers administration to the patient of the labeled radiopharmaceutical agent(s) stored in container 22. For applications in which administration system 26 comprises automated administration device 352, container 22 is operatively coupled to device 352, and the signal drives 15 administration device 352 to administer the labeled radiopharmaceutical agent(s) stored therein to the patient. Automated administration device 352 is configured to perform intravenous (IV) injection, intramuscular (IM) injection, subcutaneous injection, transdermal application, oral administration, nasal administration, inhalation, transcervical application, transrectal administration, or another type of administration known in the art. 20 (It is to be understood that although the administration signal triggers administration of the agent, for some applications automated administration device 352 does not administer the agent until a healthcare worker provides a final authorization to do so, such as to comply with regulatory safety requirements.) For applications in which administration system 26 does not comprise automated administration device 352, the administration 25 signal triggers administration of the agent by instructing a healthcare worker to manually administer the agent to the patient.

For some applications, based on administration protocol information received from data carrier 120 of radiopharmaceutical agent container 22 and/or patient-specific data carrier 24, control unit 350 customizes the administration of the labeled 30 radiopharmaceutical agent(s) contained in agent container 22. Such administration protocol information typically includes all or a portion of the administration protocol information described hereinabove with reference to Fig. 7. For some applications, administration system 26 administers a plurality of labeled radiopharmaceutical agents,

either sequentially or premixed together within a single agent container 22 (i.e., as a cocktail).

For some applications, administration system 26 administers the labeled radiopharmaceutical agent(s) responsively at least in part to acquisition of a signal 5 associated with the agent(s). For example, acquisition of the signal may comprise detection of photons emitted from the agent(s), in order to determine a radioactivity level.

For some applications, administration system 26 monitors uptake and/or clearance of the labeled radiopharmaceutical agent(s) by (a) measuring physiological parameters, e.g., from samples of blood, saliva, or secretions, e.g., urine, breath, feces, or sweat, or (b) 10 by performing an imaging procedure using imaging system 28. For some applications, these measurements are used to estimate pharmacokinetics of the radiopharmaceutical agent(s) in organs, and/or to predict optimal imaging timing (the optimal time to perform the imaging, and/or the optimal timing parameters of the imaging procedure). For some 15 applications, based on these estimates, an expected level of uptake of the radiopharmaceuticals in a target organ is determined, enabling diagnosis of pathologies based on absolute uptake levels in the target organ.

The imaging system

Reference is made to Fig. 11, which is a schematic illustration of imaging system 28, in accordance with an embodiment of the present invention. Imaging system 28 20 comprises a control unit 450, a communication element 240, a camera 452, and an imaging workstation 453. Typically, control unit 450 and imaging workstation 453 comprise one or more standard personal computers or servers with appropriate memory, communication interfaces and software for carrying out the functions prescribed by relevant embodiments of the present invention. This software may be downloaded to the 25 control unit and imaging workstation in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM.

Control unit 450 typically comprises: (a) image acquisition functionality, which is configured to drive camera 452 to perform image acquisition of the patient; (b) image reconstruction functionality, which is configured to perform an image reconstruction 30 procedure on the acquired image; (c) image analysis functionality, which is configured to perform an image analysis procedure on the reconstructed image; and (d) diagnosis

functionality, which is configured to perform a diagnostic procedure using the results of the image analysis procedure. It will be appreciated that control unit 450 may comprise a plurality of personal computers or servers, each of which performs one or more of these procedures, and that one or more of these computers or servers may be located remotely 5 from camera 452. Imaging workstation 453 displays the reconstructed images and allows the attending healthcare worker to view and manipulate the images.

As mentioned above with reference to steps 124 through 130 of Fig. 2, imaging system 28 typically customizes one or more of these procedures at least in part 10 responsively to imaging protocol information and/or patient-specific information read by communication element 240 from patient-specific data carrier 24.

For some applications, camera 452 comprises a commercially available diagnostic structural or functional camera, such as a SPECT or PET camera, and/or utilizes imaging techniques described in one or more of the patents and patent applications described hereinabove in the section entitled "Background of the Invention." Alternatively, camera 15 452 utilizes techniques described in the above-mentioned International Application PCT/IL2005/001173, in above-mentioned PCT Publication WO 05/119025, and/or in the other above-mentioned co-assigned patent applications and/or patent application publications.

In an embodiment of the present invention, camera 452 comprises a plurality of 20 detectors 454, each of which is coupled to a respective angular orientator 456. Each of the detectors comprises a plurality of gamma ray sensors, such as a pixelated CZT array, and a collimator. For example, the array may include 16x64 pixels. Control unit 450 drives, typically separately, each of the orientators to orient its respective detector in a plurality of orientations with respect to a region of interest (ROI). Control unit 450 25 produces a SPECT image from a plurality of radiation acquisitions acquired with the detectors in different relative orientations.

In an embodiment of the present invention, camera 452 is configured to begin an image acquisition procedure by performing a relatively brief, preliminary scan, and, based 30 on the results of this preliminary scan, to determine one or more parameters of the full image acquisition procedure, such as dwell time per orientation of each detector 454. Typically, this determination further takes into account imaging protocol and/or patient-specific information received by imaging system 28 from patient-specific data

carrier 24, such as the activity of the labeled radiopharmaceutical agent at the time of administration, the time of administration, the patient's BMI (which may be used to estimate a perfusion percentage), and the pharmacokinetics of the labeled radiopharmaceutical agent.

5 In an embodiment of the present invention, camera 452 is configured to individually set a total angular range of each of detectors 454 responsively to the detector's orientation with respect to the ROI. For example, at least one detector closer to the ROI (a "proximal detector" or an "inner detector") may have a greater total angular range than at least one detector further from the ROI (a "distal detector" or an "outer detector"). The distal detectors are typically located nearer to the ends of a frame holding the detectors, while the proximal detectors are typically located nearer to center of the frame. The use of narrower angular ranges for some of the detectors generally reduces the photon acquisition time spent by these detectors in orientations aimed outside of the ROI. Alternatively, at least one distal detector has a greater total angular range than at least one proximal detector. In order to reduce the total angular range for a given detector, camera 452 typically drives the associated angular orientator 456 to: (a) increase the dwell time of the detector in at least a portion of its orientations, and/or (b) reduce the angle by which the detector is moved during each orienting of the detector. For some applications, camera 452 sets the angular range of the detectors based on protocol information received 10 by imaging system 28 from patient-specific data carrier 24. For example, the number of distal and proximal detectors, and their respective angular ranges, may be specified by the protocol information, as described hereinabove with reference to Figs. 6B-E.

15 In an embodiment of the present invention, camera 452 comprises a plurality of detectors 454, each of which is coupled to a respective angular orientator 456. Each of the detectors comprises a plurality of gamma ray sensors, such as a pixelated CZT array, and a collimator. Control unit 450 drives, typically separately, each of the orientators to 20 orient its respective detector in a plurality of orientations with respect to a region of interest (ROI). Control unit 450 produces a SPECT image from a plurality of radiation acquisitions acquired with the detectors in different relative orientations.

25 In an embodiment, camera 452 is configured to drive one of orientators 456 to move its respective detector 454 through a plurality of sequential angular positions, e.g., positions 1, 2, 3, ..., 18, 19, and 20. Typically, a linear relationship relates the sequential

positions, such that, for example, positions 1, 2, 3, ..., 20 represent 1°, 2°, 3°, ..., 20°, or, 2°, 4°, 6°, ..., 40°. Alternatively, a non-linear relationship relates the sequential positions. Higher or lower angular resolutions are typically obtainable, as well.

For some applications, camera 452 steps the orientator in a first pass through a 5 subset of the positions spanning most of the range of positions, and in a second pass the camera steps the orientator through a different subset of the positions. At each position, data are acquired by the detector. For example, during the first pass, the camera may drive the orientator to step through positions 1, 5, 9, 13, and 17, and the detector acquires data at each of these positions. During the second pass, the orientator steps through 10 positions 2, 6, 10, 14, and 18. During two subsequent passes, data are acquired at the remainder of the positions. In this manner, a single-direction interlaced scan of the data is acquired by camera 452.

In an embodiment, a back-and-forth interlaced scan is acquired in which data are sampled when the orientator is moving in both directions. For example, during the first 15 pass, the camera may drive the orientator to step through positions 1, 5, 9, 13, and 17. During the second pass, the orientator steps through positions 18, 14, 10, 6, and 2. During the third pass, the orientator steps through positions 3, 7, 11, 15, and 19, while during the fourth pass, the orientator steps through positions 20, 16, 12, 8, and 4. Fifth and higher passes, if desired, typically repeat the motions used in the earlier passes.

20 For some applications, the positions in a pass are not ordered from lowest-to-highest or highest-to-lowest. For example the positions of a pass may be 1, 15, 11, 19, and 17. Typically, the positions are, however, distributed generally evenly throughout the range of positions, in order to acquire photon counts representative of the entire region of interest.

25 As appropriate for a given scanning protocol using interlaced scanning, one or more, or even all of orientators 456 are driven to step through their respective positions in an interlaced fashion.

Typically, execution of an interlaced scan as provided by these embodiments of the present invention allows an operator of camera 452, such as an imaging technician or 30 other healthcare worker, to acquire a high-resolution image of the ROI in about 105% to 115% of the amount of time as would be used if orientator 456 were stepped through the positions sequentially. (Typically, each orientation takes between about 50 and about 200

msec, depending upon the angle of the step.) The high-resolution image is completely acquired after the orientator has stepped through each of its positions. In some cases, additional value is attained by interlacing the scanning, however, as this allows the performance of dynamic studies, in which a plurality of images are acquired during a 5 respective plurality of the time periods, i.e., during each complete pass of the orientator. Although each of these images is typically of lower resolution than the high-resolution image acquired using photon counts acquired during all of the passes, the images nevertheless have sufficient resolution to produce clinically-meaningful data for each time period of a dynamic study.

10 For some applications, interlacing the scanning allows an operator to see an initial, lower-resolution scan of the ROI. If, for example, an adjustment of any form is desired, this can often be seen within the first few seconds of a scan. The present scan is terminated, the adjustment made, and a second scan initiated. In the absence of interlacing, it is typically necessary to wait until a scan has completed until an assessment 15 of the scan's results can be made.

For some applications, it is desirable to know whether the patient has moved during a scan. Patient movement is one reason for lower quality images, and when identified it can typically be corrected by suitable instruction and then a second scanning procedure initiated. Interlaced scanning, as provided by these embodiments of the present 20 invention, allows the operator to immediately assess whether there has been patient movement between one pass and a subsequent pass. In an embodiment, the imaging system displays to an operator the scans obtained from the various passes in rapid succession at the same location on a monitor. As appropriate, the imaging system cycles quickly through the scans repeatedly (e.g., pass 1, pass 2, pass 3, pass 4, pass 1, pass 2, 25 pass 3, pass 4...), e.g., displaying each scan for between about 0.2 and about 2 seconds, allowing an operator to see whether there is jitter between successive scans. If so, patient movement is typically the cause and image acquisition is repeated. For some applications, the scan is acquired in exactly two passes, e.g., the orientator steps through positions 1, 3, 5, ..., 19 during a first pass, and through positions 2, 4, 6, ..., 20 during a 30 second pass, or through positions 20, 18, 16, ..., 2 during the second pass.

Images acquired using these techniques, or other non-interlacing techniques described herein, are generally used to perform one or more of the following image

reconstructions: (a) reconstruction of intensity image, (b) reconstruction of intensity over time, followed by fitting a model of the kinetics (which describe for each voxel a parameter set describing its time curve), and followed by presenting a three-dimensional map of the parameters, and/or (c) direct reconstruction of a three-dimensional parametric representation, without performing a reconstruction of an intensity map, typically by plugging an equation of a kinetic model into a reconstruction algorithm, and generating a result directly in terms of the value of the parameters per voxel (the parameters may include, for example, flow, diffusion coefficients, metabolism rate, or bio-clearance rate).

The radiopharmaceutical dispensing system

Reference is made to Fig. 12, which is a schematic illustration of automated radiopharmaceutical dispensing system 20, in accordance with an embodiment of the present invention. System 20 comprises a control unit 500, at least one robot 502, and at least one communication element 504, which, for some applications, is coupled to robot 502. Control unit 500 typically comprises a conventional personal computer running a conventional operating system, such as Windows XP, with appropriate memory, communication interfaces and software for carrying out the functions described herein. This software may be downloaded to the control unit in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM. Control unit 500 is in communication with other elements of system 10, for example via management and control component 150. The control unit notifies appropriate elements of the system upon successful completion of dispensing of a dose.

At least one radiolabeled mother vial 104 is placed in a shielded vials complex 505 of dispensing system 20. Control unit 500 authenticates the mother vial, by actuating communication element 504 to read authentication information stored in data carrier 106, and/or by verifying a coded signature 256 coupled to the mother vial, as described hereinbelow in the section entitled "Signature." Upon successful authentication, control unit 500 actuates communication element 504 to read radiopharmaceutical-related information from data carrier 106 of the mother vial, including the radiopharmaceutical agent type, isotope type, batch, lot, radiochemical purity (RCP), preparation time, and half-life information. Dispensing system 20 assays the radioactivity per unit volume of the labeled radiopharmaceutical agent contained in the mother vial. Robot 502 picks up an empty syringe 506 from a syringe tray 508, draws a predetermined amount of solution

from mother vial 104, and brings the syringe to a dose calibrator 510. The syringe used for the assaying is typically discarded into a waste container 512. Typically, robot 502 brings the mother vial to a weighing station 507 for verification that the vial contains the indicated solution volume.

5 Dispensing system 20 receives a patient-specific dose request for at least one specific labeled radiopharmaceutical agent, having a specific dose, radioactivity, and solution volume. Such a dose is typically calculated by dose calculation sub-system 156 of dose calculation system 152, as described hereinabove with reference to Fig. 5, and/or by patient management system 160, described hereinabove with reference to Fig. 4.
10 Alternatively or additionally, dispensing system 20 is configured to customize, modify, or verify the dose. Further alternatively, dispensing system 20 receives the order from another hospital or radiopharmacy information system, or the order is manually inputted into system 20.

To fill the request, control unit 500 calculates a required volume of the labeled
15 radiopharmaceutical agent and a required volume of saline solution for dilution, if any. To perform this calculation, control unit 500 uses (a) information read from data carrier 106 (such as the half-life of the labeling isotope of the labeled radiopharmaceutical agent), and (b) the assayed radioactivity of the labeled radiopharmaceutical agent. Alternatively, dose calculation sub-system 156 performs all or a portion of this calculation.

20 For some applications, control unit 500 authenticates mother vial license information read from data carrier 106, in order to verify that a license is available for dispensing the requested dose. Dispensing proceeds only if a license is available and authenticated. The use of such a license generally provides increased quality control of the imaging process, by verifying that only approved manufacturers (or distributors) are
25 able to provide radiopharmaceutical agents for use with system 10. A lack of precision in any aspect of an imaging procedure, which may result from the use of an agent that has not been tested and approved for use with system 10, often causes a deterioration of the resultant image quality and/or ability to make accurate and/or quantitative diagnoses.

Control unit 500 actuates robot 502 to pick up an empty radiopharmaceutical agent
30 container 22 from tray 508. Typically, but not necessarily, container 22 comprises a syringe, such as described hereinabove with reference to Figs. 9A-H. Container 22 has coupled thereto a data carrier 120. For some applications, syringes 506 and containers 22

are stored in a single tray, as shown in Fig. 12, while for other applications, they are stored in separate trays. Robot 502 typically authenticates container 22, by actuating communication element 504 to read authentication information stored in data carrier 120 and/or verifying coded signature 245 coupled to the container, as described hereinbelow 5 in the section entitled "Signature."

Robot 502 removes the needle cap from container 22, turns the container over, and brings container 22 to the appropriate mother vial 104. The robot actuates the container to draw the calculated volume of labeled radiopharmaceutical agent from the mother vial, typically by inserting the needle of container 22 through a membrane of mother vial 104, 10 and withdrawing a plunger of container 22 until the desired volume of agent has been drawn from the mother vial. The robot typically brings the syringe to dose calibrator 510 for quality control assaying of radioactivity. If necessary, robot 502 brings container 22 to a saline vial 514, and actuates the container to draw the required volume of saline solution into the container. Robot 502 replaces the needle cap on the container, and turns 15 the container over. Alternatively, saline solution is drawn prior to drawing the labeled radiopharmaceutical agent from mother vial 104. For some applications, a needle of the container 22 is changed between drawings.

For dispensing a cocktail of labeled radiopharmaceutical agents, each having a respective dose, robot 502 repeats these steps for a plurality of mother vials 104, typically 20 changing the needle of container 22 between drawings. During dispensing of such a cocktail, robot 502 typically draws first from the mother vial containing the lower or lowest radiation labeled radiopharmaceutical agent, such as to reduce any effect the assaying of the first agent may have on the assaying of the subsequent agent(s).

System 20 typically performs a quality control check on the dispensed 25 radiopharmaceutical solution to confirm that the solution contains the desired dose(s) of the radiopharmaceutical agent(s) and radioactivity level.

Control unit 500 activates communication element 504 to write radiopharmaceutical information to data carrier 120 of container 22, as described hereinabove with reference to Fig. 8 and step 118 of Fig. 2. For some applications, the 30 data carrier is coupled to the container prior to placement of the container in dispensing system 20, while for other applications, robot 502 couples a data carrier to each container during or after the dispensing process. Similarly, for some applications in which coded

signature 256 is provided, the coded signature is attached to container 22 prior to placement of the container in dispensing system 20, while for other applications, robot 502 couples a coded signature to each container during or after the dispensing process.

Robot 502 brings the filled container to a shield body tray 530, and inserts the 5 container into a container shield 532. The robot picks up a shield cap 534 from a shield cap tray 536, and secures it to container shield 532. For some applications, data carrier 120 is coupled to shield 532 or cap 534, rather than directly to container 22. Alternatively, separate data carriers 120 are coupled to the container and the shield or cap.

In an embodiment of the present invention, dispensing system 20 comprises a print 10 area 540, at which dispensing system 20 prints and attaches at least one conventional label to container 22, shield 532, and/or cap 534, in order to comply with regulatory labeling requirements. The dispensing system typically prints yet another conventional label for placement on a basket that holds a plurality of containers 22 for transport within or between healthcare facilities.

15 After the dispensing of container 22 has been completed, robot 502 brings the container to a completed container tray (tray not shown in the figure).

In an embodiment of the present invention, dispensing system 20 comprises at least one diluted mother vial which has a greater volume than a conventional mother vial. For example, the diluted mother vial may have a volume of at least about 10 ml, e.g., at 20 least about 20 ml, such as 21 ml, while a conventional mother vial may have a volume of less than 10 ml, e.g., less than 7 ml, such as 5.8 ml. The labeled radiopharmaceutical agent solution from a conventionally-sized mother vial 104 is transferred to the diluted mother vial, and the balance of the additional volume of the diluted mother vial is filled with saline solution. The resulting diluted solution is used by dispensing system 20 to fill 25 containers 22 with low-dose labeled radiopharmaceutical agents useful for performing low-dose imaging procedures, such as those described in the above-mentioned International Application IL/2005/001173, in above-mentioned PCT Publication WO 05/119025, or in one or more of the other co-assigned patent applications incorporated herein by reference. Alternatively, the resulting lower-dose solution is used for 30 time-dependent administration protocols, pursuant to which a desired total dose is divided into several sub-doses for sequential administration over time. For mechanical handling and administration reasons, each sub-dose must have a minimum volume, e.g., at least 1

ml.

The information contained in data carrier 106 of conventionally-sized mother vial 104 is transferred to a data carrier 106 of the dilution mother vial, with appropriate adjustments to reflect the diluted dose of the labeled radiopharmaceutical agent.

5 In an embodiment of the present invention, a method for automatically dispensing a labeled radiopharmaceutical agent comprises providing a mother vial having a volume of at least 10 ml, e.g., at least 20 ml; filling the mother vial with at least 5 ml of a non-diluted labeled radiopharmaceutical agent, and with at least 5 ml of saline solution; placing the mother vial in automated radiopharmaceutical dispensing system 20; and
10 dispensing at least one dose from the mother vial to a container. For some applications, dispensing system 20 further dilutes the dose by dispensing saline solution to the container from a saline solution container.

It is noted that dispensing system 20 is theoretically able to dispense similar low doses to containers 22 by drawing a small volume of labeled radiopharmaceutical agent
15 from a conventionally-sized mother vial, and diluting the agent with saline solution drawn from saline vial 512, as described above. However, the drawing of such a small volume may present mechanical challenges for achieving precise volumes within acceptable variations.

Reference is made to Figs. 13A-C, which are schematic illustrations of a system
20 for carrying out a data transfer process, in accordance with an embodiment of the present invention. In this embodiment, information is transferred directly from data carrier 106 of mother vial 104 to data carrier 120 of container 22 while container 22 draws the labeled radiopharmaceutical agent from mother vial 104. As shown in Fig. 13A, container 22 is lowered to mother vial 104 (which is contained within shielding 520 of vials complex
25 505), as indicated by an arrow 522. As shown in Fig. 13B, as container 22 draws labeled radiopharmaceutical solution from mother vial 104, data carrier 120 of the container is positioned in a vicinity of data carrier 106 of the mother vial. Container 22 is raised from mother vial 104, as indicated by an arrow 524 in Fig. 13C. Information transfer takes place during one or more of the steps illustrated in Figs. 13A-C.

30 For some applications, information is transferred to data carrier 120 of container 22 during assaying of the contents of the container at dose calibrator 510.

In an embodiment of the present invention, dispensing system 20 is configured to dispense to a plurality of containers 22 for a single patient, or to a plurality of independent chambers within a single container 22 (such as first and second chambers 282A and 282B, described hereinabove with reference to Fig. 9C). For some applications, the plurality of 5 containers are permanently coupled to one another, while for other applications the plurality of containers are removably coupled to one another. Alternatively, the plurality of containers are not coupled to one another, in which case they may be stored in association with one another, e.g., in a single tray.

For some applications, dispensing system 20 utilizes one or more of the dispensing 10 techniques described in the references mentioned hereinabove in the Background of the Invention section, *mutatis mutandis*.

In an embodiment of the present invention, system 10 does not comprise dispensing system 20. System 10 is instead electronically or manually interfaced with a conventional radiopharmacy. Patient management system 160 places orders with the 15 radiopharmacy for a particular dose of a labeled radiopharmaceutical agent for a particular patient. Upon dispensing of the dose into a conventional container, such as a syringe, data carrier 120 is physically coupled to the container, and information is written to the data carrier, such as the identity of the labeled radiopharmaceutical agent, the time of dispensing, the measured radioactivity level, and/or other information described herein as 20 being contained in the data carrier, such as with reference to Fig. 8. For some applications, system 10 comprises a module for automatically measuring the radioactivity level and recording the information in the data carrier. Optionally, the module is in communication with system 10, such as via management control component 150, and receives additional patient-specific or protocol-related information from system 10, and 25 records the information in data carrier 120. For some applications, the radiopharmacy dispenses the labeled radiopharmaceutical agent to one of the novel radiopharmaceutical agent containers 22 described herein.

The radioisotope elution system

Reference is made to Fig. 14, which is a schematic illustration of a radioisotope 30 automatic elution system 600, in accordance with an embodiment of the present invention. System 600 automatically elutes a radioisotope, such as technetium Tc-99m, into radioisotope vials 610. The radioisotope is used for radiolabeling the unlabeled

radiopharmaceutical agent, as described hereinabove with reference to step 110 of Fig. 2. Vials 610 are coupled to radioisotope data carriers 612 containing information about the radioisotope, such as a vial code, the time of preparation, the activity at the time of preparation, and total solution volume. Labels 612 are computer-communicatable, and 5 typically comprise an RFID tag, smart card, disk-on-key (e.g., a USB key), compact disc, minidisk, disposable computer-readable medium, or other electronic memory, or a machine-readable code, e.g., a barcode. For some applications, information contained in data carrier 612 is encrypted for enabling authentication. Alternatively or additionally, data carrier 612 and/or vial 610 comprise coded signature 256, as described hereinabove. 10 The coded signature typically comprises an encrypted signature and/or a color-coded signature, as described hereinbelow in the section entitled "Signature."

The automatic elution process typically begins with a determination by dose calculation system 152 (Fig. 5) of an optimal elution frequency, for example:

- 18 hours, 6 hours, 18 hours, 6 hours, ... ;
- 15 • 23 hours, 1 hour, 23 hours, 1 hour, ... ;
- 18 hours, 1 hour, 5 hours, 18 hours, 1 hour, 5 hours, ... ; or
- 18 hours, 6 hours, 23 hours, 1 hour, 18 hours, 6 hours, 23 hours, 1 hour, ...
 ..

Dose calculation system 152 electronically notifies a control system 616 of elution 20 system 600 of the desired elution frequency. For applications in which the radioisotope comprises Tc-99m, it will be appreciated that the ratio of Tc-99 to Tc-99m, which is determined by the elution frequency, is important for molecular imaging by an antibody, and there is generally an optimal range of the ratio of Tc-99 to Tc-99m, which should be taken into consideration when preparing Tc-99m with an antibody. Typically, control 25 system 616 comprises one or more standard personal computers or servers with appropriate memory, communication interfaces and software for carrying out the functions prescribed by relevant embodiments of the present invention. This software may be downloaded to the control system in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM.

30 Sterile, empty vials 610 of predetermined volumes (e.g., 10 ml or 20 ml), and typically comprising caps 618, are placed on a conveyor belt 620. A first robot 622 places

a shield 624 on each vial 610. Alternatively, the vials 610 are manually shielded. Conveyor belt 620 moves shielded vial 610 into position under a radioisotope generator 626, such as a TC-99m generator. At a required elution time, a second robot 628 lifts the shielded empty vial 610, and, under sterile conditions, removes cap 618 and engages the 5 shielded empty vial 610 with generator 626.

Upon engagement of vial 610 with generator 626, both a first electronic valve 630 of a saline tank 632 and a second electronic valve 634 of generator 626 open, and vial 610 is filled, while a flow meter 636 monitors the amount of saline flow. After flow of a predetermined volume, control system 616 automatically shuts first electronic valve 630 10 of saline tank 632 and second electronic valve 634 of generator 626.

Filled, shielded vial 610 is automatically disengaged from generator 626, and is automatically sealed under sterile conditions with a shielded seal 638. Filled, shielded vial 610 is lowered back to conveyor belt 620. The conveyor belt moves filled, shielded vial 610 past an assaying and labeling station 640, which assays and labels the vial with 15 data carrier 612, a barcode 642, and/or coded signature 256. For some applications, coded signature 256 is placed on data carrier 612, while for other applications it is placed on vial 610. For still other applications, separate coded signatures 256 are placed on both vial 610 and data carrier 612, and are used to match the vial with the data carrier. For example, a color-coded signature may be printed on vial 610, either prior to the elution or 20 together with the application of data carrier 612, and an encrypted signature may be stored in the data carrier 612. Alternatively, the encrypted signature may be printed.

It will be appreciated that the elution process is subject to modifications and alterations based on communication and information that is received from system 10. For example, a log book of elution system 600 may specify a Tc-99m vial of 1000 mCi, yet a 25 communication request from dose calculation system 152 may modify the order to be a Tc-99m vial of 200 mCi, based on new requirements, e.g., low-dose administration.

The mother vial preparation system

Reference is made to Fig. 15, which is a schematic illustration of a mother vial preparation system 700, in accordance with an embodiment of the present invention. 30 System 700 automatically labels mother vials 104, containing unlabeled radiopharmaceutical agents, with appropriate radioisotopes. System 700 attaches a data

carrier 106 to each mother vial 104, and writes the information to the data carrier that is described hereinabove with reference to Fig. 7. Alternatively, the manufacturer or distributor attaches data carrier 106 to mother vial 104, and writes at least a portion of the information to the carrier.

5 Prior to beginning the radiolabeling process, a control unit 702 of system 700 authenticates radioisotope vial 610 and mother vial 104, and verifies that radioisotope vial 610 contains the correct radioisotope at the correct radioactivity, and that mother vial 104 contains the correct unlabeled radiopharmaceutical agent. For some applications, such authentication and/or verification is performed by authenticating coded signature 256 of
10 data carrier 612 of radioisotope vial 610. For some applications, such authentication includes authentication of a commercial license associated with the use of mother vial 104. Typically, control unit 702 comprises one or more standard personal computers or servers with appropriate memory, communication interfaces and software for carrying out the functions prescribed by relevant embodiments of the present invention. This software
15 may be downloaded to the control unit in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM.

Conveyor belt 620 carries shielded radioisotope vial 610 from radioisotope automatic elution system 600 to mother vial preparation system 700. Alternatively, for embodiments in which elution system 600 is not provided, the radioisotope vial is
20 manually placed on conveyor belt 620. The conveyor belt brings vial 610 to a radioisotope filling point 710.

System 700 typically comprises a plurality of dose preparation platforms 712, each of which contains premixed mother vials 104 containing unlabeled radiopharmaceutical agents that require radiolabeling with the radioisotope contained in radioisotope vial 610,
25 e.g., Tc-99m. In the example shown in Fig. 15, preparation platforms 712 comprise a Tc-99m-teboroxime dose preparation platform, a Tc-99m-pertechnetate dose preparation platform, a Tc-99m-sestamibi dose preparation platform, and a Tc-99m-MDP dose preparation platform.

A robot 720 picks up a syringe 722 from a first syringe platform 724, or a
30 micro-syringe 726 from a second syringe platform 728, and travels along a second conveyer belt 730 to filling point 710. It will be appreciated that other types syringes and/or other dispensing tools may also be used. Upon reaching filling point 710, syringe

722 or 726 draws a predetermined amount of radioisotope solution from radioisotope vial 610. The robot typically travels to an assay station 732, which assays the radioisotope solution. Syringe 722 or 726 is then discarded at a discard station 734.

Robot 720 picks up another syringe 722 or 726 from the platform 724 or 728, fills 5 the syringe with a predetermined amount of the radioisotope from vial 610, and travels along second conveyor belt 730 to one of dose preparation platforms 712. At the dose preparation platform, the syringe injects a predetermined amount of radioisotope into mother vial 104 of the dose preparation platform, thereby labeling the unlabeled radiopharmaceutical agent contained in the mother vial.

10 Robot 720 discards the syringe at discard station 734, picks up a new syringe, draws a predetermined amount of solution from labeled mother vial 104, and assays the solution at assay station 732, in order to determine the radioactivity of the labeled radiopharmaceutical agent contained in mother vial 104. Following the assaying, robot 720 discards the syringe at discard station 734. Typically, system 700 performs one or 15 more quality control procedures on the labeled radiopharmaceutical agent.

System 700 updates data carrier 106 of mother vial 104 with radiolabeling information, such as the time of labeling, and the activity of the radioisotope at the time of labeling, the total solution volume in the mother vial, and the ratio of radioisotopes (e.g., Tc-99m to Tc-99) at the time of labeling, for applications in which the unlabeled 20 radiopharmaceutical agent is labeled with more than one radioisotope.

It is noted that system 700 is configurable to vary a radioactivity of the radioisotope used to label a given radiopharmaceutical agent in order to produce labeled radiopharmaceutical agents of various levels of radioactivity (for example, Tc-99m-teboroxime of 500 mCi and Tc-99m-teboroxime of 50 mCi). For some 25 applications, system 700 comprises at least one cocktail dose preparation platform 736, for labeling a cocktail of radiopharmaceutical agents (for example, Tl-201-thallous chloride, Tc-99m-sestamibi, and I-123-BMIPP).

It will be appreciated that the mother vial preparation process is subject to modifications and alterations based on communication and information that is received 30 from system 10. For example, a log book of system 700 may specify a mother vial of 500 mCi, yet a communication request from dose calculation system 152 may modify the order to be a mother vial of 200 mCi, based on new requirements, e.g., low-dose

administration.

The exercise room

In an embodiment of the present invention, system 10 comprises at least one exercise room, which comprises one or more pieces of exercise equipment, typically including at least one treadmill. The exercise room, and the equipment therein, is typically in communication with one or more elements of system 10, such as patient-specific data carrier 24, management and control component 150, administration system 26, data carrier 120 of radiopharmaceutical agent container 22, and/or imaging system 28. For example, the exercise room may report the duration, time, and type of exercise to imaging system 28, administration system 26, and/or management control component 150, for synchronizing the exercise with administration and imaging. For some applications, the exercise room receives instructions regarding the duration, time, and/or type of exercise to be performed for a given patient, and schedules an appropriate exercise session in a log book. For some applications, the exercise room sends the patient an SMS-like message notifying the patient of the scheduled session, and/or reminding the patient about a scheduled session. For some applications in which data carrier 24 is integrated into watch or bracelet 170, as described hereinabove with reference to Fig. 3, watch or bracelet 170 is configured to receive and display the SMS-like message to the patient.

20 *Signature*

In accordance with an embodiment of the present invention, coded signature 256 comprises a signature encrypted using an encryption algorithm, which is either proprietary or known in the art, e.g., Advanced Encryption Standard (AES), Data Encryption Standard (DES), or Triple DES (3DES). Typically, the encryption algorithm utilizes a 25 symmetric key cipher, as is known in the art.

For some applications, coded signature 256 is stored in one of the data carriers described herein. Alternatively or additionally, the coded signature is printed on the apparatus, e.g., as a barcode.

For some applications, coded signature 256 comprises a color-coded signature, 30 which is implemented using techniques described in the above-mentioned US Patent Application Publication 2004/0156081 to Bril et al. Techniques described in the '081

publication include the use of an encrypted image comprising an array of printed positions formed using a group of inks each of which has a predetermined spectrum. The positions are selected to form a predetermined image, either real or virtual, when the image is viewed through an optical processor. The optical processor may further use a distortion, 5 such as a distorted grating or a distorted lens. The correct image is the spectrum, as distorted by the optical processor. An image formed using inks having the same colors as experienced by the human eye, or even by a standard spectrometer, will fail to form the correct predetermined image. Alternatively or additionally, special inks may be used, so that no two ink combinations are exactly alike, and only registered ink combinations 10 provide the correct spectrum. Furthermore, the special inks may be mixtures of 5 or more colors.

Fig. 16A illustrates color spectra 800 of several dyes, for example dyes B, D1, G, D2, and R, each having a well-defined spectral peak, as described in the '081 publication. When dye B and dye G are mixed, the human eye may see a color substantially the same 15 as the color of dye D1. When dye D1 and dye D2 are mixed, the human eye may see a color substantially the same as the color of dye G.

Fig. 16B illustrates a color-coded signature 802, as described in the '081 publication. A color patch 804, which to the human eye may seem a plain orange, for example, may have a first portion 806A, consisting of dye B and dye G, combined to form 20 a hue which is substantially the same as that of dye D1, and a second portion 806B, consisting of dye D1. To the human eye, the color-coded signature 802 appears as a homogeneous patch.

An optical processor 820 comprises an imaging spectrograph, which comprises a grating 822 and, typically, a lens 824. In the example shown in Fig. 16B, the 25 spectrograph produces three structures: a structure 821 formed by diffraction of dye D1 through the grating, a structure 823 formed by diffraction of dye G, and a structure 825 formed by diffraction of dye B. Optical processor 220 thus reveals the authentic spectra of the color-coded signature 802.

For some applications, optical processor 820 comprises two lenses 824 of 30 substantially equal power, one to create a parallel beam at the input to the grating, just before the grating, and one to create an image at the focal point after the grating. Alternatively, a single lens 824, having twice the power of the two lenses, may be placed

just before or just after the grating.

For some applications, a more complex color coding is achieved by using a distorted lens or a distorted grating, such that spectral structure 821, 823, and 825 may be reproduced only when an optical processor having the exact distortion is used. It will be
5 appreciated that a single hue may be produced by mixing several dyes, for example, 3, 5, or 10. It will be appreciated that each printing house may be allocated only a specific mix of dyes, so that no two printing houses may have identical dye combinations, and no two printing houses may reproduce the same color-coded signatures 802.

For some applications, color-coded signature 802 is printed directly on an element
10 of system 10, for example, on radiopharmaceutical agent container 22 (Fig. 1), or on radioisotope vial 610 (Fig. 14). Alternatively or additionally, a label, for example, mother vial data carrier 106 or data carrier 120 (Fig. 1) is color-coded, or includes a color-coded patch or pattern, operative as color-coded signature 802.

For some applications, an encrypted signature 256 and a color-coded signature 802
15 are combined. The resulting color-coded machine-readable signature 256 is authenticated by optical processor 820. For example, an encrypted signature may be provided on a label colored with a coded color. Alternatively or additionally, encrypted signature 256 is printed on a color-coded background, or with color-coded dyes. Alternatively or additionally, coded signature 256 comprises a color-coded barcode. For some
20 applications, the color-coded barcode may appear black or another color to the eye, but reveal a unique spectrum to optical processor 820. For some applications, the color-coded machine-readable signature further comprises a date, to prevent the recycling or re-use of signatures.

Physical key

25 Reference is made to Fig. 17, which is a schematic illustration of a computer-readable medium 850, a portion of which is shaped so as to define a physical key 852, in accordance with an embodiment of the present invention. A communication element 854 is shaped so as to define a dedicated slot 856 having a geometry matching that of key 852. Only keys having the particular geometry of slot 856 can be inserted into
30 the slot. Key 852 thus enables authentication of computer-readable medium 850. Computer-readable medium 850 may comprise, for example, a disk-on-key apparatus or a

chip, having, for example, a USB-type connector.

For some applications, patient-specific data carrier 24 comprises computer-readable medium 850, and a communication element of imaging system 28 and/or administration system 26 is shaped so as to define slot 856. Alternatively or 5 additionally, healthcare worker identity tag 208 comprises computer-readable medium 850, and workstation 200, elution system 600, dispensing system 20, administration system 26, and/or imaging system 28 is shaped so as to define slot 856. For some applications, computer-readable medium 850 further comprises coded signature 256, as described hereinabove, while for other applications, key 852 is relied upon in lieu of 10 coded signature 256.

For some applications, authentication, as described herein, is alternatively or additionally based on additional parameters, such as a manufacturer's attribute.

In an embodiment of the present invention, information is transferred from one element of system 10 to another element thereof by physically transferring an electronic 15 information-carrying chip from one element to the other. For example, upon administration of the labeled radiopharmaceutical agent contained in container 22, information may be transferred from data carrier 120 to patient-specific data carrier 24 by physically transferring a memory chip of data carrier 120 to data carrier 24.

Managing Compton residuals

Reference is made to Fig. 18, which is a graph showing particle energy vs. photon 20 count at a detector 454 of camera 452 of imaging system 28 (Fig. 11), in accordance with an embodiment of the present invention. In this embodiment, dose calculation sub-system 156 of radiopharmaceutical dose calculation system 152, described hereinabove with 25 reference to Fig. 5, takes Compton residuals into consideration when calculating doses of a first and a second labeled radiopharmaceutical agent to be mixed together in a cocktail, or to be separately administered for the same image acquisition procedure. If the first agent were to be provided at a relatively high dose and the second agent were to be provided at a lower dose, the first agent would produce a first peak 900A around a first energy level E^1 , and the second agent would produce a second peak 902 around a second 30 energy level E^2 . A Compton residual 904A produced by the first agent at least partially masks second peak 902. For some applications, in order to prevent such masking, dose

calculation sub-system 156 reduces the dose of the first agent, thereby producing a first peak 900B and a corresponding Compton residual 904B having lower counts than initial first peak 900A and Compton residual 904A, respectively. Compton residual 904B is sufficiently low so as not to mask second peak 902. By using techniques described 5 hereinabove and/or incorporated herein by reference, camera 452 is sufficiently sensitive to acquire sufficient counts emitted from the lower dose of the second agent. For example, the first and second agents may comprise MIBI-Tc and thallium, respectively, which emit energy at 140 KeV and 72 KeV, respectively.

Alternatively, calculation sub-system 156 determines that the dose of the first 10 labeled radiopharmaceutical agent cannot be reduced sufficiently to prevent such Compton masking. To make such a determination, the sub-system typically takes into consideration constraints applied by the physical properties of the first agent, patient-specific information, and/or camera 452. The sub-system may thus determine that the two agents must be prepared as separate doses for non-simultaneous administration. 15 Alternatively, the sub-system determines that the dose of the second agent is to be increased, so as to prevent the masking. To make such a determination, the sub-system typically takes into consideration constraints applied by the physical properties of the first agent, patient-specific information, camera 452, and/or safety and/or regulatory requirements.

20 *Information-bearing radiopharmaceuticals*

In an embodiment of the present invention, a portion of the patient, radiopharmaceutical, and/or protocol information described herein is chemically stored together with a labeled radiopharmaceutical agent in a container, such as radiopharmaceutical agent container 22 or mother vial 104. For some applications, such 25 information is chemically stored by providing a chemical indicative of and/or encoding the information, and mixing the chemical with the radiopharmaceutical agent. Alternatively, such information is chemically stored by attaching a chemical marker indicative of the information to the radiopharmaceutical agent, or otherwise chemically modifying the radiopharmaceutical agent to store the information. The 30 information-indicative chemical indicator (i.e., chemical or chemical marker) has properties which are machine-readable, for example, using optical, spectral, fluorescence, or isotope emission techniques.

For some applications, the information is stored by setting a level of a parameter of the chemical indicator, such as concentration or radioactivity, which level is indicative of the information. For example, a plurality of concentrations 0, A_1 , A_2 , A_3 , ..., A_{\max} may be defined, each of which represents a respective value. At all of the defined 5 concentrations, the chemical indicator is biologically inert and/or safe in the body, and does not affect the sterility and/or properties of the radiopharmaceutical agent. The plurality of concentrations are sufficiently different from one another so as to be independently measurable and identifiable, such as by measuring a spectral signature of the chemical indicator. For some applications, a plurality of different chemical indicators 10 are used, each of which has defined levels of a parameter representing respective values. The values represented by the plurality of chemical indicators together represent the information.

For some applications, the level of the parameter of the chemical indicator changes over time, e.g., the radioactivity of the chemical indicator declines because of 15 radioactive decay, thereby providing an indication of elapsed time. Such elapsed time may be used, for example, to determine the timing of preparation of the radiopharmaceutical agent and/or subsequent processes, as well as validating whether such timing is within an allowed time window.

For some applications, dispensing system 20 applies the code to the labeled 20 radiopharmaceutical agent and/or container 22 during the dispensing process, and administration system 26 and/or imaging system 28 reads and verifies the stored information. A dedicated reader may be provided for such reading, or a camera of imaging system 28 may be configured to perform such reading.

The scope of the present invention includes embodiments described in the 25 following applications, which are assigned to the assignee of the present application and are incorporated herein by reference. In an embodiment, techniques and apparatus described in one or more of the following applications are combined with techniques and apparatus described herein:

- International Application PCT/IL2005/001173, filed November 9, 2005;
- International Application PCT/IL2005/000572, filed June 1, 2005;
- International Application PCT/IL2005/000575, filed June 1, 2005;

- International Application PCT/IL2005/001215, filed November 16, 2005;
- US Provisional Application 60/625,971, filed November 9, 2004;
- US Provisional Application 60/628,105, filed November 17, 2004;
- US Provisional Application 60/630,561, filed November 26, 2004;
- 5 • US Provisional Application 60/632,236, filed December 2, 2004;
- US Provisional Application 60/632,515, filed December 3, 2004;
- US Provisional Application 60/635,630, filed December 14, 2004;
- US Provisional Application 60/636,088, filed December 16, 2004;
- US Provisional Application 60/640,215, filed January 3, 2005;
- 10 • US Provisional Application 60/648,385, filed February 1, 2005;
- US Provisional Application 60/648,690, filed February 2, 2005;
- US Provisional Application 60/675,892, filed April 29, 2005;
- US Provisional Application 60/691,780, filed June 20, 2005;
- US Provisional Application 60/700,318, filed July 19, 2005;
- 15 • US Provisional Application 60/700,299, filed July 19, 2005;
- US Provisional Application 60/700,317, filed July 19, 2005;
- US Provisional Application 60/700,753, filed July 20, 2005;
- US Provisional Application 60/700,752, filed July 20, 2005;
- US Provisional Application 60/702,979, filed July 28, 2005;
- 20 • US Provisional Application 60/720,034, filed September 26, 2005;
- US Provisional Application 60/720,652, filed September 27, 2005;
- US Provisional Application 60/720,541, filed September 27, 2005;
- US Provisional Application 60/750,287, filed December 13, 2005;
- US Provisional Application 60/750,334, filed December 15, 2005; and/or
- 25 • US Provisional Application 60/750,597, filed December 15, 2005.

As used in the present application, including in the claims, a "clinical

"environment" means any facility or institution in which at least one of radiopharmaceutical preparation, dispensing, and administration occur, including, for example, a radiopharmaceutical manufacturing facility, a pharmacy, a hospital, a doctor's clinic, a day clinic, an out-patient clinic, a laboratory, and a geriatric center.

5 It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the
10 foregoing description.

CLAIMS

1. Apparatus for use with at least one labeled radiopharmaceutical agent, the apparatus comprising:
 - a container containing the at least one labeled radiopharmaceutical agent; and
 - 5 a portable computer-communicatable data carrier associated with the container, the data carrier containing imaging protocol information for use with the at least one labeled radiopharmaceutical agent.
2. The apparatus according to claim 1, wherein the apparatus comprises a device configured to write the imaging protocol information to the data carrier.
- 10 3. The apparatus according to claim 1, wherein the data carrier additionally contains administration protocol information useful for administering the at least one labeled radiopharmaceutical agent.
4. The apparatus according to claim 1, wherein the imaging protocol information comprises instructions for performing an imaging procedure using the at least one labeled radiopharmaceutical agent.
- 15 5. The apparatus according to claim 1, wherein the imaging protocol information comprises an identifier of an imaging protocol.
6. The apparatus according to claim 1, wherein the imaging protocol information comprises a parameter of the at least one labeled radiopharmaceutical agent.
- 20 7. The apparatus according to claim 1, wherein the imaging protocol information comprises a parameter useful for configuring at least one aspect of an imaging procedure performed using the at least one labeled radiopharmaceutical agent.
8. The apparatus according to claim 1, wherein the container contains a single dose of the radiopharmaceutical agent, which dose is appropriate for use with the imaging protocol information.
- 25 9. The apparatus according to claim 1, wherein the container contains a plurality of labeled radiopharmaceutical agents mixed together.
10. The apparatus according to claim 1, wherein the container is shaped so as to define a plurality of chambers, each of which contains a respective one of a plurality of labeled radiopharmaceutical agents.

11. The apparatus according to any one of claims 1-10,
wherein the data carrier comprises a first data carrier, which contains a first identifier value,
wherein the apparatus further comprises a second computer-communicatable data carrier, which contains a second identifier value, and
5 wherein the apparatus is configured to operate responsively to a detection of a correspondence between the first and second identifier values.
12. The apparatus according to claim 11, wherein at least one of the first and second data carriers is configured to perform the detection of the correspondence.
- 10 13. The apparatus according to claim 11, wherein the apparatus comprises a correspondence-detection element configured to perform the detection of the correspondence.
14. The apparatus according to claim 11, wherein at least one of the first and second data carriers contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.
15. The apparatus according to claim 11, wherein at least one of the first and second identifier values comprises an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.
16. The apparatus according to claim 11, wherein exactly one of the first and second data carriers comprises a coupling mechanism configured to be coupled to a patient to whom the labeled radiopharmaceutical agent is to be administered.
- 20 17. The apparatus according to claim 11, wherein the apparatus comprises an imaging system comprising imaging functionality, the imaging system configured, responsively to the detection of the correspondence, to drive the imaging functionality to perform an imaging procedure using the at least one labeled radiopharmaceutical agent.
- 25 18. The apparatus according to any one of claims 1-10, wherein the data carrier is physically coupled to the container.
19. The apparatus according to claim 18, wherein the data carrier contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered, and wherein the imaging protocol information comprises imaging protocol information selected for the patient.

20. The apparatus according to claim 19, wherein the imaging protocol information comprises an identifier of an imaging protocol.
21. The apparatus according to claim 19, wherein the imaging protocol information comprises imaging protocol information customized for the patient.
- 5 22. The apparatus according to any one of claims 1-10, wherein the imaging protocol information comprises SPECT imaging protocol information.
23. The apparatus according to claim 22, wherein the SPECT imaging protocol information comprises dynamic SPECT imaging protocol information.
- 10 24. The apparatus according to claim 23, wherein the SPECT imaging protocol information comprises at least one kinetic parameter of the at least one labeled radiopharmaceutical agent, the at least one kinetic parameter useful for performing a dynamic SPECT imaging procedure using the at least one labeled radiopharmaceutical agent.
- 15 25. The apparatus according to any one of claims 1-10, comprising an imaging system, which comprises:
 - a communication element, configured to read the imaging protocol information from the data carrier; and
 - 20 a control unit, comprising imaging functionality, which is configured to perform an imaging procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.
26. The apparatus according to claim 25, wherein the imaging system comprises a camera, wherein the imaging functionality comprises image acquisition functionality, and wherein the image acquisition functionality is configured to perform an image acquisition procedure using the camera, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.
- 25 27. The apparatus according to claim 26, wherein the image acquisition functionality configures a total acquisition time of the image acquisition procedure at least in part responsively to the imaging protocol information.
- 30 28. The apparatus according to claim 26, wherein the camera comprises a plurality of detectors, and wherein the image acquisition functionality is configured to configure, at

least in part responsively to the imaging protocol information, at least one motion of at least one of the detectors during the image acquisition procedure.

29. The apparatus according to claim 26, wherein the control unit is configured to configure, at least in part responsively to the imaging protocol information, a waiting time 5 between administration of the labeled radiopharmaceutical agent and commencement of the image acquisition procedure.

30. The apparatus according to claim 26, wherein the image acquisition functionality is configured to perform a gated image acquisition procedure at least in part responsively to the imaging protocol information.

10 31. The apparatus according to claim 25, wherein the imaging functionality comprises image reconstruction functionality, and wherein the image reconstruction functionality is configured to perform an image reconstruction procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

15 32. The apparatus according to claim 25, wherein the imaging functionality comprises image analysis functionality, and wherein the image analysis functionality is configured to perform an image analysis procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

20 33. The apparatus according to claim 25, wherein the imaging functionality comprises diagnosis functionality, and wherein the diagnosis functionality is configured to perform a diagnostic procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

25 34. The apparatus according to claim 25, wherein the imaging procedure includes a three-dimensional dynamic imaging study, and wherein the imaging functionality is configured to perform the three-dimensional dynamic imaging study, and to configure the study at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

35. The apparatus according to any one of claims 1-10, wherein the data carrier is not 30 physically coupled to the container, and wherein the data carrier contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

36. The apparatus according to claim 35, wherein the data carrier comprises a coupling mechanism configured to be coupled to the patient.
37. The apparatus according to claim 35, wherein the data carrier comprises a first data carrier, and wherein the apparatus further comprises a second computer-communicatable data carrier physically coupled to the container, the second data carrier containing radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent.
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38. Apparatus for use with at least one labeled radiopharmaceutical agent, the apparatus comprising:
 - 10 a container containing the at least one labeled radiopharmaceutical agent; and a computer-communicatable data carrier associated with the container, the data carrier containing authenticatable information regarding a commercial license for use of SPECT imaging protocol information with the at least one labeled radiopharmaceutical agent.
- 15 39. The apparatus according to claim 38, comprising an imaging system, which comprises:
 - 20 a communication element, configured to read the authenticatable license information from the data carrier;
 - a control unit, comprising imaging functionality, the control unit configured to: authenticate the authenticatable license information, and only upon authentication, drive the imaging functionality to perform an imaging procedure using the SPECT imaging protocol information.
40. The apparatus according to claim 38, wherein the apparatus comprises a device configured to write the authenticatable license information to the data carrier.
- 25 41. The apparatus according to any one of claims 38-40, wherein the data carrier is physically coupled to the container.
42. Apparatus comprising a portable computer-communicatable data carrier containing authenticatable information regarding a commercial license for use of SPECT imaging protocol information.
- 30 43. The apparatus according to claim 42, wherein the data carrier additionally contains patient information regarding a patient upon whom an imaging procedure using the

SPECT imaging protocol information is to be performed.

44. The apparatus according to claim 42, wherein the authenticatable license information is encrypted.

45. The apparatus according to claim 42, wherein the apparatus comprises a device 5 configured to write the authenticatable license information to the data carrier.

46. The apparatus according to claim 42, wherein the data carrier comprises a coupling mechanism configured to be coupled to a patient upon whom an imaging procedure using the SPECT imaging protocol information is to be performed.

47. The apparatus according to any one of claims 42-46, comprising an imaging 10 system, which comprises:

a communication element, configured to read the authenticatable license information from the data carrier;

a control unit, comprising imaging functionality, the control unit configured to: authenticate the authenticatable license information, and

15 only upon authentication, drive the imaging functionality to perform an imaging procedure using the SPECT imaging protocol information.

48. Apparatus comprising:

a first portable computer-communicatable data carrier containing a first identifier value;

20 a second portable computer-communicatable data carrier containing a second identifier value; and

an imaging system comprising imaging functionality, the imaging system configured, responsively to a detection of a correspondence between the first and second identifier values, to drive the imaging functionality to perform an imaging procedure on a 25 patient.

49. The apparatus according to claim 48, wherein at least one of the first and second data carriers is configured to perform the detection of the correspondence.

50. The apparatus according to claim 48, wherein the imaging system comprises a correspondence-detection element configured to perform the detection of the 30 correspondence.

51. The apparatus according to claim 48, wherein at least one of the first and second

data carriers contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

52. The apparatus according to claim 48, wherein at least one of the first and second identifier values comprises an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

53. The apparatus according to claim 48, wherein one of the first and second data carriers comprises a coupling mechanism configured to be coupled to a patient to whom the labeled radiopharmaceutical agent is to be administered.

54. The apparatus according to claim 48, wherein the apparatus comprises a device 10 configured to write at least one of the first and second identifier values to the respective first and second data carriers.

55. The apparatus according to any one of claims 48-54, wherein at least one of the first and second data carriers contains radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent, 15 wherein the imaging system comprises a communication element, configured to read the radiopharmaceutical information from the at least one of the data carriers, and wherein the imaging system is configured to configure the imaging procedure at least in part responsively to the read radiopharmaceutical information.

56. The apparatus according to claim 55, wherein the apparatus comprises a container 20 containing the at least one labeled radiopharmaceutical agent.

57. The apparatus according to claim 56, wherein one of the first and second data carriers is physically coupled to the container.

58. The apparatus according to any one of claims 48-54, wherein the imaging functionality comprises a nuclear camera.

25 59. The apparatus according to claim 58, wherein the nuclear camera comprises a SPECT camera.

60. Apparatus for use with first and second portable computer-communicatable data carriers containing first and second identifier values, respectively, the apparatus comprising an imaging system, which comprises:

30 imaging functionality; and

a control unit configured to drive the imaging functionality to perform an imaging procedure on a patient, responsively to a detection of a correspondence between the first and second identifier values.

61. The apparatus according to claim 60, wherein the imaging system comprises a 5 correspondence-detection element configured to perform the detection of the correspondence.

62. Apparatus for use with at least one labeled radiopharmaceutical agent for administration to a patient, the apparatus comprising:

10 a container containing the at least one labeled radiopharmaceutical agent;
a first computer-communicatable data carrier physically coupled to the container, the first data carrier containing radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent; and

15 a second portable computer-communicatable data carrier containing patient information regarding the patient, and imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

63. The apparatus according to claim 62, wherein the imaging protocol information comprises SPECT imaging protocol information.

64. The apparatus according to claim 62, wherein the patient information comprises an identifier of the patient.

20 65. The apparatus according to claim 62, wherein the second data carrier comprises a coupling mechanism configured to be coupled to the patient.

66. The apparatus according to claim 62, wherein the first data carrier contains a first patient identifier, wherein the patient information contained in the second data carrier comprises a second patient identifier, and comprising an administration system, which 25 comprises:

a first communication element, configured to read the first patient identifier from the first data carrier;

a second communication element, configured to read the second patient identifier from the second data carrier; and

30 a control unit, configured to compare the first patient identifier to the second patient identifier, and, upon detecting a match, generate an administration signal that

triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

67. The apparatus according to claim 62, wherein the first data carrier contains a first protocol identifier, wherein the imaging protocol information contained in the second data carrier comprises a second protocol identifier, and comprising an administration system, which comprises:

a communication element, configured to read the first and second protocol identifiers from the first and second data carriers, respectively; and

10 a control unit, configured to compare the first protocol identifier to the second protocol identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

68. The apparatus according to claim 62, wherein the first data carrier contains a first protocol identifier, wherein the imaging protocol information contained in the second data carrier comprises a second protocol identifier, and comprising an administration system, which comprises:

a first communication element, configured to read the first protocol identifier from the first data carrier;

20 a second communication element, configured to read the second protocol identifier from the second data carrier; and

a control unit, configured to compare the first protocol identifier to the second protocol identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

25 69. The apparatus according to claim 62, comprising an administration system, which comprises:

a communication element; and

a control unit, configured to:

30 generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container, and

drive the communication element to transmit information regarding the administration to the second data carrier.

70. The apparatus according to claim 62, wherein the apparatus comprises a device configured to write the imaging protocol information to the first data carrier.

71. The apparatus according to claim 62, wherein the apparatus comprises a device configured to write the patient information to the second data carrier.

5 72. The apparatus according to any one of claims 62-71, wherein the imaging protocol information comprises imaging protocol information selected for the patient.

73. The apparatus according to claim 72, wherein the imaging protocol information comprises an identifier of an imaging protocol.

10 74. The apparatus according to claim 72, wherein the imaging protocol information comprises imaging protocol information customized for the patient.

75. The apparatus according to any one of claims 62-71, wherein the first data carrier contains a first patient identifier, wherein the patient information contained in the second data carrier includes a second patient identifier, and comprising an administration system, which comprises:

15 a communication element, configured to read the first and second patient identifiers from the first and second data carriers, respectively; and

a control unit, configured to compare the first patient identifier to the second patient identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent 20 contained in the container.

76. The apparatus according to claim 75, wherein the administration system comprises an automated administration device, configured to administer the at least one labeled radiopharmaceutical agent to the patient upon being triggered by the administration signal.

25 77. The apparatus according to claim 75, wherein the control unit is configured to generate the administration signal to trigger the administration of the at least one labeled radiopharmaceutical agent by instructing a healthcare worker to administer the at least one labeled radiopharmaceutical agent to the patient.

78. Apparatus for use with at least one labeled radiopharmaceutical agent for 30 administration to a patient, the apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent;

a computer-communicatable data carrier associated with the container, the data carrier containing data regarding at least one of: the labeled radiopharmaceutical agent and the patient; and

a SPECT imaging system comprising:

5

a communication element, configured to read the data; and

10

a control unit, configured to utilize the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

79. The apparatus according to claim 78, wherein the data carrier contains the data regarding the labeled radiopharmaceutical agent.

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80. The apparatus according to claim 78, wherein the data carrier contains the data regarding the patient.

81. The apparatus according to claim 78, wherein the control unit is configured to utilize the read data to customize the administration of the labeled radiopharmaceutical agent.

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82. The apparatus according to claim 78, wherein the control unit is configured to utilize the read data to customize the acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered.

83. The apparatus according to claim 78, wherein the control unit is configured to utilize the read data to customize the reconstruction of the SPECT image.

25

84. The apparatus according to claim 78, wherein the control unit is configured to utilize the read data to customize the analysis of the SPECT image.

85. The apparatus according to claim 78, wherein the control unit is configured to utilize the read data to customize the diagnosis of a condition of the patient based at least in part on the analysis.

30

86. The apparatus according to any one of claims 78-85, wherein the apparatus comprises a device configured to write the data to the data carrier.

87. A SPECT imaging system for use with a container containing at least one labeled radiopharmaceutical agent for administration to a patient, and data regarding at least one of: the labeled radiopharmaceutical agent and the patient, the system comprising:

a communication element, configured to read the data; and

5 a control unit, configured to utilize the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in
10 part on the analysis.

88. The system according to claim 87, wherein the system comprises a device configured to write the data to the container.

89. An automated radiopharmaceutical dispensing system for use with a container and a computer-communicatable container data carrier associated with the container, the
15 system comprising:

a robot, configured to manipulate the container;

a communication element; and

a control unit, configured to:

receive radiopharmaceutical information regarding at least one labeled
20 radiopharmaceutical agent, the radiopharmaceutical information selected from the group consisting of: imaging protocol information for use with the at least one labeled radiopharmaceutical agent, and authenticatable information regarding a commercial license for use of an imaging protocol with the at least one labeled radiopharmaceutical agent,

25 receive patient information regarding a patient,

drive the robot to automatically dispense a dose of the labeled radiopharmaceutical agent to the container, and

30 drive the communication element to transmit to the container data carrier at least a portion of the radiopharmaceutical information and at least a portion of the patient information.

90. The system according to claim 89, wherein the control unit is configured to receive the radiopharmaceutical information regarding a plurality of labeled

radiopharmaceutical agents, and drive the robot to automatically dispense respective doses of the labeled radiopharmaceutical agents to the container.

91. The system according to claim 89, wherein the patient information includes an identifier of an imaging protocol assigned to the patient for performance using the dose, 5 and wherein the control unit is configured to drive the communication element to transmit the imaging protocol identifier to the container data carrier.

92. The system according to claim 89, wherein the control unit is configured to drive the communication element to transmit to the container data carrier at least one of: a time of dispensing of the labeled radiopharmaceutical agent to the container, and information 10 regarding a radioactivity of the dose at the time of dispensing.

93. The system according to claim 89, comprising:

a mother vial that contains the labeled radiopharmaceutical agent prior to dispensing thereof; and

15 a computer-communicatable mother vial data carrier associated with the mother vial, which mother vial data carrier contains the radiopharmaceutical information,

wherein the control unit is configured to receive the radiopharmaceutical information from the mother vial data carrier.

94. The system according to any one of claims 89-93, wherein the radiopharmaceutical information comprises the imaging protocol information.

20 95. The system according to claim 94, wherein the imaging protocol information comprises SPECT imaging protocol information.

96. The system according to claim 95, wherein the imaging protocol information comprises at least one kinetic parameter of the at least one labeled radiopharmaceutical agent.

25 97. The system according to any one of claims 89-93, wherein the radiopharmaceutical information comprises the authenticatable information regarding the commercial license.

98. The system according to claim 97, wherein the information regarding the commercial license comprises information regarding the commercial license for use of a 30 SPECT imaging protocol with the at least one labeled radiopharmaceutical agent.

99. The system according to claim 97, wherein the control unit is configured to

authenticate the authenticatable license information, and to drive the robot to automatically dispense the dose only upon authentication.

100. Apparatus for use with a container, the apparatus comprising:

5 a mother vial having a volume of at least 10 ml, which contains at least 5 ml of a non-diluted labeled radiopharmaceutical agent, and at least 5 ml of saline solution; and an automated radiopharmaceutical dispensing system, configured to contain the mother vial, and to dispense at least one dose from the mother vial to the container.

101. A method comprising:

10 placing at least one labeled radiopharmaceutical agent in a container; associating a portable computer-communicatable data carrier with the container; and writing, to the data carrier, imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

102. The method according to claim 101, comprising writing, to the data carrier, administration protocol information useful for administering the at least one labeled radiopharmaceutical agent.

103. The method according to claim 101, wherein writing the imaging protocol information comprises writing instructions for performing an imaging procedure using the at least one labeled radiopharmaceutical agent.

104. The method according to claim 101, wherein writing the imaging protocol information comprises writing an identifier of an imaging protocol.

105. The method according to claim 101, wherein writing the imaging protocol information comprises writing a parameter of the at least one labeled radiopharmaceutical agent.

106. The method according to claim 101, wherein writing the imaging protocol information comprises writing a parameter useful for configuring at least one aspect of an imaging procedure performed using the at least one labeled radiopharmaceutical agent.

107. The method according to claim 101, wherein placing comprises placing a single dose of the radiopharmaceutical agent in the container, which dose is appropriate for use 30 with the imaging protocol information.

108. The method according to claim 101, wherein placing comprises placing, in the container, a plurality of labeled radiopharmaceutical agents mixed together.

109. The method according to claim 101, wherein the container is shaped so as to define a plurality of chambers, and wherein placing the at least one labeled radiopharmaceutical agent in the container comprises placing a plurality of labeled radiopharmaceutical agents in respective chambers.

110. The method according to any one of claims 101-109, wherein associating the data carrier comprises associating a first data carrier with the container, and wherein the method comprises:

10 writing a first identifier value to the first data carrier;
 writing a second identifier to a second computer-communicatable data carrier;
 detecting a correspondence between the first and second identifier values; and
 performing an operation responsively to the detecting.

111. The method according to claim 110, wherein detecting comprises detecting the correspondence by at least one of the first and second data carriers.

112. The method according to claim 110, wherein detecting comprises detecting by a correspondence-detection element separate from the first and second data carriers.

113. The method according to claim 110, comprising writing, to at least one of the first and second data carriers, an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

114. The method according to claim 110, wherein writing at least one of the first and second identifier values comprises writing an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

115. The method according to claim 110, comprising coupling exactly one of the first and second data carriers to a patient to whom the labeled radiopharmaceutical agent is to be administered.

116. The method according to claim 110, wherein performing the operation comprises, responsively to the detecting of the correspondence, performing an imaging procedure using the at least one labeled radiopharmaceutical agent.

30 117. The method according to any one of claims 101-109, wherein associating the data carrier with the container comprises physically coupling the data carrier to the container.

118. The method according to claim 117, wherein the data carrier contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered, and wherein writing the imaging protocol information comprises writing imaging protocol information selected for the patient.

5 119. The method according to claim 118, wherein writing the imaging protocol information comprises writing an identifier of an imaging protocol.

120. The method according to claim 118, wherein writing the imaging protocol information comprises writing imaging protocol information customized for the patient.

121. The method according to any one of claims 101-109, wherein writing the imaging 10 protocol information comprises writing SPECT imaging protocol information.

122. The method according to claim 121, wherein writing the SPECT imaging protocol information comprises writing dynamic SPECT imaging protocol information.

123. The method according to claim 122, wherein writing the SPECT imaging protocol information comprises writing at least one kinetic parameter of the at least one labeled 15 radiopharmaceutical agent, the at least one kinetic parameter useful for performing a dynamic SPECT imaging procedure using the at least one labeled radiopharmaceutical agent.

124. The method according to any one of claims 101-109, comprising:
reading the imaging protocol information from the data carrier; and

20 performing an imaging procedure, and configuring the procedure at least in part responsively to the imaging protocol information read from the data carrier.

125. The method according to claim 124, wherein performing the imaging procedure comprises performing an image acquisition procedure, and configuring the procedure at least in part responsively to the imaging protocol information read from the data carrier.

25 126. The method according to claim 125, wherein performing the image acquisition procedure comprises configuring a total acquisition time of the image acquisition procedure at least in part responsively to the imaging protocol information.

127. The method according to claim 125, wherein performing the image acquisition procedure comprises performing the image acquisition procedure using a camera having a 30 plurality of detectors, and configuring, at least in part responsively to the imaging protocol information, at least one motion of at least one of the detectors during the image

acquisition procedure.

128. The method according to claim 125, wherein performing the image acquisition procedure comprises configuring, at least in part responsively to the imaging protocol information, a waiting time between administration of the labeled radiopharmaceutical agent and commencement of the image acquisition procedure.

129. The method according to claim 125, wherein performing the image acquisition procedure comprises performing a gated image acquisition procedure at least in part responsively to the imaging protocol information.

130. The method according to claim 124, wherein performing the imaging procedure comprises performing an image reconstruction procedure, and configuring the procedure at least in part responsively to the imaging protocol information read from the data carrier.

131. The method according to claim 124, wherein performing the imaging procedure comprises performing an image analysis procedure, and configuring the procedure at least in part responsively to the imaging protocol information read from the data carrier.

132. The method according to claim 124, wherein performing the imaging procedure comprises performing a diagnostic procedure, and configuring the procedure at least in part responsively to the imaging protocol information read from the data carrier.

133. The method according to claim 124, wherein performing the imaging procedure comprises performing a three-dimensional dynamic imaging study, and configuring the study at least in part responsively to the imaging protocol information read from the data carrier.

134. The method according to any one of claims 101-109, wherein associating the data carrier with the container does not comprise physically coupling the data carrier to the container, and comprising writing, to the data carrier, an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

135. The method according to claim 134, comprising coupling the data carrier to the patient.

136. The method according to claim 134, wherein associating the data carrier comprises associating a first data carrier with the container, and comprising writing, to a second computer-communicatable data carrier, radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent, and physically coupling the second data

carrier to the container.

137. A method comprising:

placing at least one labeled radiopharmaceutical agent in a container;

associating a computer-communicatable data carrier with the container; and

5 writing, to the data carrier, authenticatable information regarding a commercial license for use of SPECT imaging protocol information with the at least one labeled radiopharmaceutical agent.

138. The method according to claim 137, comprising:

reading the authenticatable license information from the data carrier;

10 authenticating the authenticatable license information; and

only upon authentication, performing an imaging procedure using the SPECT imaging protocol information.

139. The method according to any one of claims 137-138, wherein associating comprises physically coupling the data carrier to the container.

15 140. A method comprising:

providing a portable computer-communicatable data carrier; and

writing, to the data carrier, authenticatable information regarding a commercial license for use of SPECT imaging protocol information.

141. The method according to claim 140, comprising writing, to the data carrier, patient

20 information regarding a patient upon whom an imaging procedure using the SPECT imaging protocol information is to be performed.

142. The method according to claim 140, wherein writing the authenticatable license information comprises encrypting the authenticatable license information.

143. The method according to claim 140, comprising:

25 reading the authenticatable license information from the data carrier;

authenticating the authenticatable license information; and

only upon authentication, performing an imaging procedure using the SPECT imaging protocol information.

144. The method according to any one of claims 140-143, comprising coupling the data

30 carrier to a patient upon whom an imaging procedure using the SPECT imaging protocol

information is to be performed.

145. A method comprising:

writing first and second identifier values to first and second computer-communicatable data carriers, respectively;

5 detecting a correspondence between the first and second identifier values; and
perform an imaging procedure on a patient responsively to the detecting.

146. The method according to claim 145, wherein detecting comprises detecting the correspondence by at least one of the first and second data carriers.

147. The method according to claim 145, wherein detecting comprises detecting by a 10 correspondence-detection element separate from the first and second data carriers.

148. The method according to claim 145, comprising writing, to at least one of the first and second data carriers, an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

149. The method according to claim 145, wherein writing at least one of the first and 15 second identifier values comprises writing an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

150. The method according to claim 145, comprising coupling one of the first and second data carriers to a patient to whom the labeled radiopharmaceutical agent is to be administered.

20 151. The method according to any one of claims 145-150, comprising:
writing, to at least one of the first and second data carriers, radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent;
reading the radiopharmaceutical information from the at least one of the data carriers; and

25 configuring the imaging procedure at least in part responsively to the read radiopharmaceutical information.

152. The method according to claim 151, comprising placing the at least one labeled radiopharmaceutical agent in a container.

153. The method according to claim 152, comprising physically coupling one of the 30 first and second data carriers to the container.

154. The method according to any one of claims 145-150, wherein performing the imaging procedure comprises performing a nuclear imaging procedure.

155. The method according to claim 154, wherein performing the nuclear imaging procedure comprises performing a SPECT imaging procedure.

5 156. A method for use with at least one labeled radiopharmaceutical agent for administration to a patient, the method comprising:

placing at least one labeled radiopharmaceutical agent in a container;

physically coupling a first computer-communicatable data carrier to the container;

writing, to the first data carrier, radiopharmaceutical information regarding the at

10 least one labeled radiopharmaceutical agent; and

writing, to a second portable computer-communicatable data carrier, patient information regarding the patient, and imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

157. The method according to claim 156, wherein writing the imaging protocol information comprises writing SPECT imaging protocol information.

158. The method according to claim 156, wherein writing the patient information comprises writing an identifier of the patient.

159. The method according to claim 156, comprising coupling the second data carrier to the patient.

20 160. The method according to claim 156, wherein writing the patient information to the second data carrier comprises writing a second patient identifier to the second data carrier, and comprising:

writing a first patient identifier to the first data carrier;

25 reading the first and second patient identifiers from the first and second data carriers, respectively; and

comparing the first patient identifier to the second patient identifier, and, upon detecting a match, generating an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

161. The method according to claim 156, wherein writing the imaging protocol information to the second data carrier comprises writing a second protocol identifier to the second data carrier, and comprising:

writing a first protocol identifier to the first data carrier;

reading the first and second protocol identifiers from the first and second data carriers, respectively; and

comparing the first protocol identifier to the second protocol identifier, and, upon

5 detecting a match, generating an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

162. The method according to claim 156, comprising:

generating an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container; and

10 transmitting information regarding the administration to the second data carrier.

163. The method according to any one of claims 156-162, wherein writing the imaging protocol information to the second data carrier comprises writing imaging protocol information selected for the patient.

164. The method according to claim 163, wherein writing the imaging protocol

15 information comprises writing an identifier of an imaging protocol.

165. The method according to claim 163, wherein writing the imaging protocol information comprises writing imaging protocol information customized for the patient.

166. The method according to any one of claims 156-162, wherein writing the patient

information to the second data carrier comprises writing a second patient identifier to the

20 second data carrier, and comprising:

writing a first patient identifier to the first data carrier;

reading the first and second patient identifiers from the first and second data carriers, respectively; and

comparing the first patient identifier to the second patient identifier, and, upon

25 detecting a match, generating an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

167. The method according to claim 166, comprising automatically administering the at least one labeled radiopharmaceutical agent to the patient upon triggering by the administration signal.

30 168. The method according to claim 166, wherein generating the administration signal comprises instructing a healthcare worker to administer the at least one labeled

radiopharmaceutical agent to the patient.

169. A method comprising:

placing, in a container, at least one labeled radiopharmaceutical agent for administration to a patient;

5 associating a computer-communicatable data carrier with the container;

writing data to the data carrier regarding at least one of: the labeled radiopharmaceutical agent and the patient;

reading the data from the data carrier at a SPECT imaging system;

utilizing the read data to customize at least one function of the system selected 10 from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

170. The method according to claim 169, wherein writing the data comprises writing 15 the data regarding the labeled radiopharmaceutical agent.

171. The method according to claim 169, wherein writing the data comprises writing the data regarding the patient.

172. The method according to claim 169, wherein utilizing the read data comprises utilizing the read data to customize the administration of the labeled radiopharmaceutical 20 agent.

173. The method according to claim 169, wherein utilizing the read data comprises utilizing the read data to customize the acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered.

174. The method according to claim 169, wherein utilizing the read data comprises 25 utilizing the read data to customize the reconstruction of the SPECT image.

175. The method according to claim 169, wherein utilizing the read data comprises utilizing the read data to customize the analysis of the SPECT image.

176. The method according to any one of claims 169-175, wherein utilizing the read data comprises utilizing the read data to customize the diagnosis of a condition of the 30 patient based at least in part on the analysis.

177. A method for use with a container containing at least one labeled radiopharmaceutical agent for administration to a patient, and data regarding at least one of: the labeled radiopharmaceutical agent and the patient, the method comprising:

reading the data at a SPECT imaging system; and

5 utilizing the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

10 178. The method according to claim 177, comprising writing the data to the container.

179. A method for use with a container and a computer-communicatable container data carrier associated with the container, the method comprising:

15 receiving, by an automated radiopharmaceutical dispensing system, radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent, the radiopharmaceutical information selected from the group consisting of: imaging protocol information for use with the at least one labeled radiopharmaceutical agent, and authenticatable information regarding a commercial license for use of an imaging protocol with the at least one labeled radiopharmaceutical agent;

20 receiving, by the dispensing system, patient information regarding a patient; automatically robotically dispensing, by the dispensing system, a dose of the labeled radiopharmaceutical agent to the container; and

transmitting to the container data carrier, by the dispensing system, at least a portion of the radiopharmaceutical information and at least a portion of the patient information.

25 180. The method according to claim 179, wherein receiving the radiopharmaceutical information comprises receiving the radiopharmaceutical information regarding a plurality of labeled radiopharmaceutical agents, and wherein dispensing comprises dispensing respective doses of the labeled radiopharmaceutical agents to the container.

181. The method according to claim 179, wherein the patient information includes an identifier of an imaging protocol assigned to the patient for performance using the dose, and wherein transmitting comprises transmitting the imaging protocol identifier to the container data carrier.

182. The method according to claim 179, wherein transmitting comprises transmitting to the container data carrier at least one of: a time of dispensing of the labeled radiopharmaceutical agent to the container, and information regarding a radioactivity of the dose at the time of dispensing.

5 183. The method according to claim 179, wherein receiving the radiopharmaceutical information comprises:

providing, to the dispensing system, a mother vial that contains the labeled radiopharmaceutical agent prior to dispensing thereof, and a computer-communicatable mother vial data carrier associated with the mother vial, which mother vial data carrier 10 contains the radiopharmaceutical information; and

receiving the radiopharmaceutical information from the mother vial data carrier.

184. The method according to any one of claims 179-183, wherein receiving the radiopharmaceutical information comprises receiving the imaging protocol information.

185. The method according to claim 184, wherein receiving the imaging protocol 15 information comprises receiving SPECT imaging protocol information.

186. The method according to claim 185, wherein receiving the imaging protocol information comprises receiving at least one kinetic parameter of the at least one labeled radiopharmaceutical agent.

187. The method according to any one of claims 179-183, wherein receiving the 20 radiopharmaceutical information comprises receiving the authenticatable information regarding the commercial license.

188. The method according to claim 187, wherein receiving the information regarding the commercial license comprises receiving information regarding the commercial license for use of a SPECT imaging protocol with the at least one labeled radiopharmaceutical 25 agent.

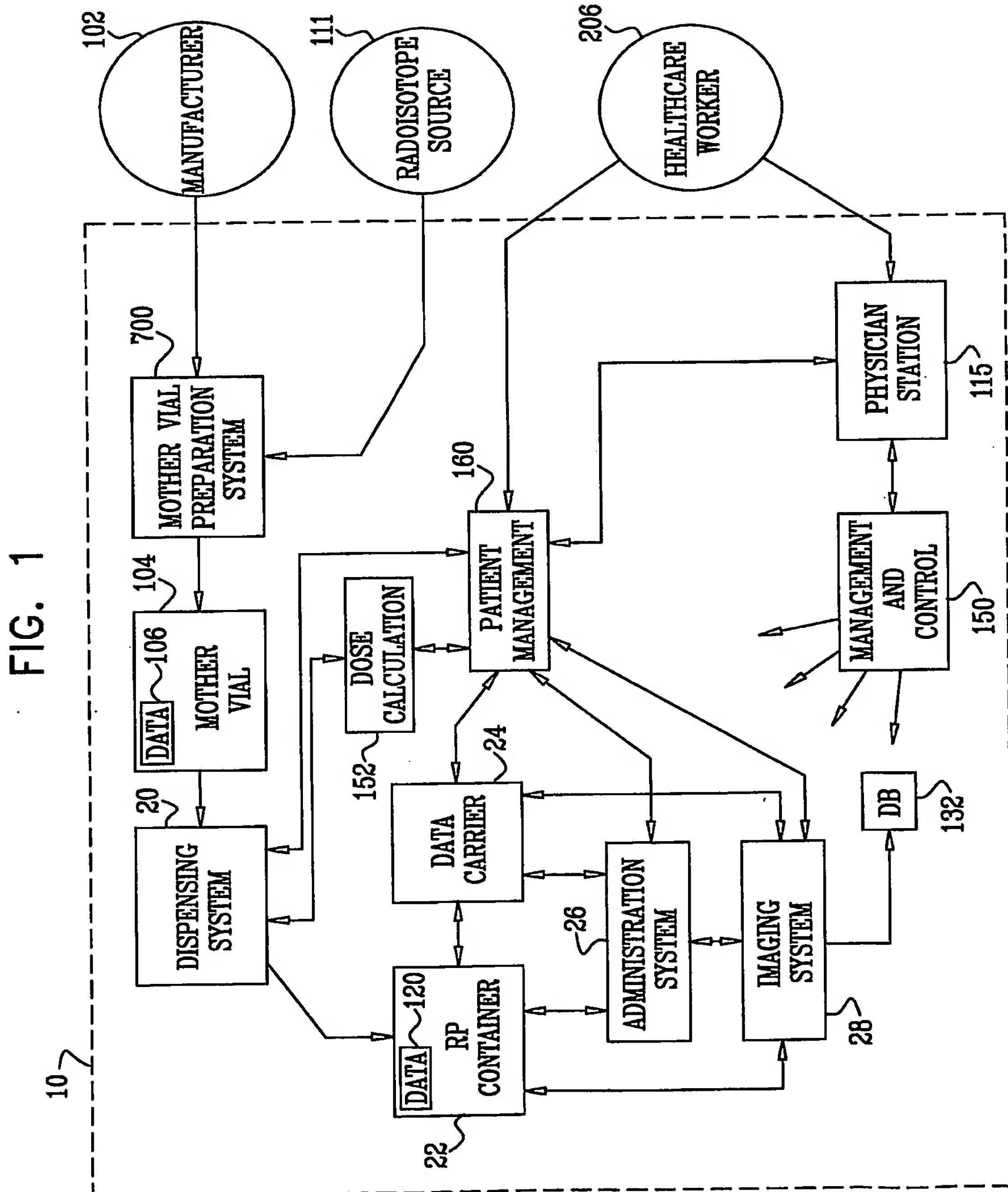
189. The method according to claim 187, wherein dispensing comprises authenticating the authenticatable license information, and dispensing the dose only upon authentication.

190. A method for automatically dispensing a labeled radiopharmaceutical agent to a container, comprising:

30 providing a mother vial having a volume of at least 10 ml;
filling the mother vial with at least 5 ml of a non-diluted labeled

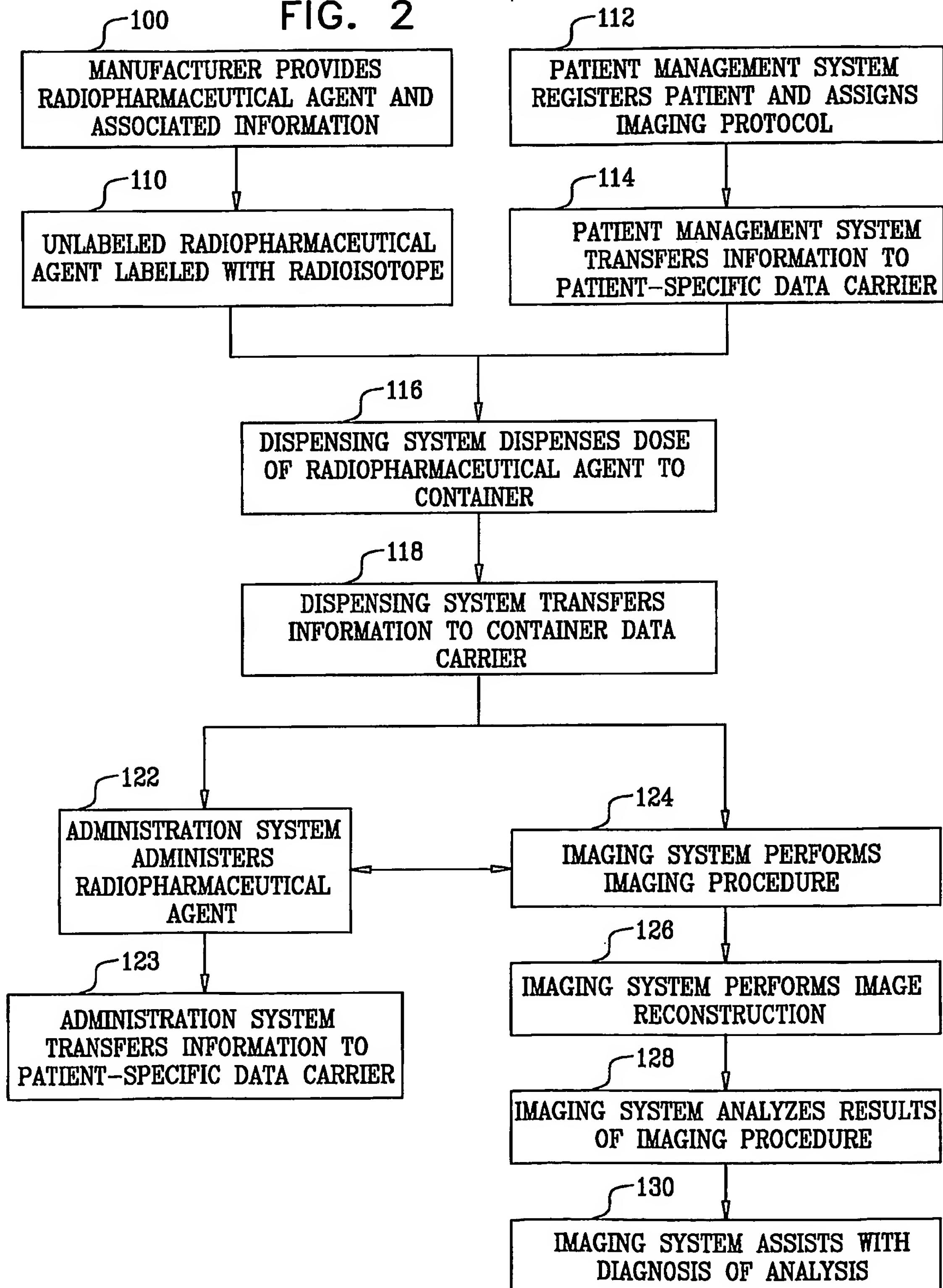
radiopharmaceutical agent, and with at least 5 ml of saline solution;
placing the mother vial in an automated radiopharmaceutical dispensing system;
and
dispensing at least one dose from the mother vial to the container.

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FIG. 2



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FIG. 3

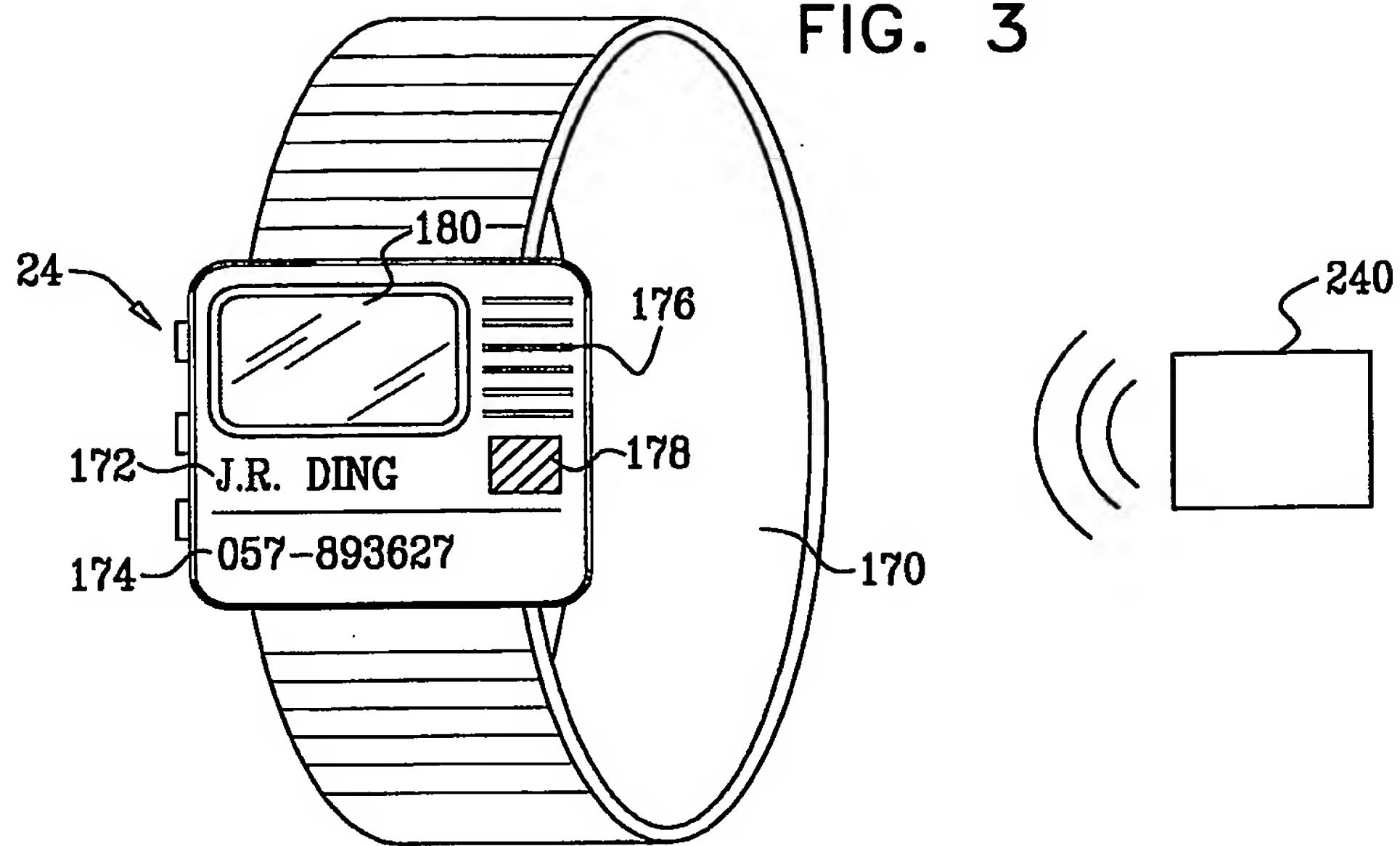
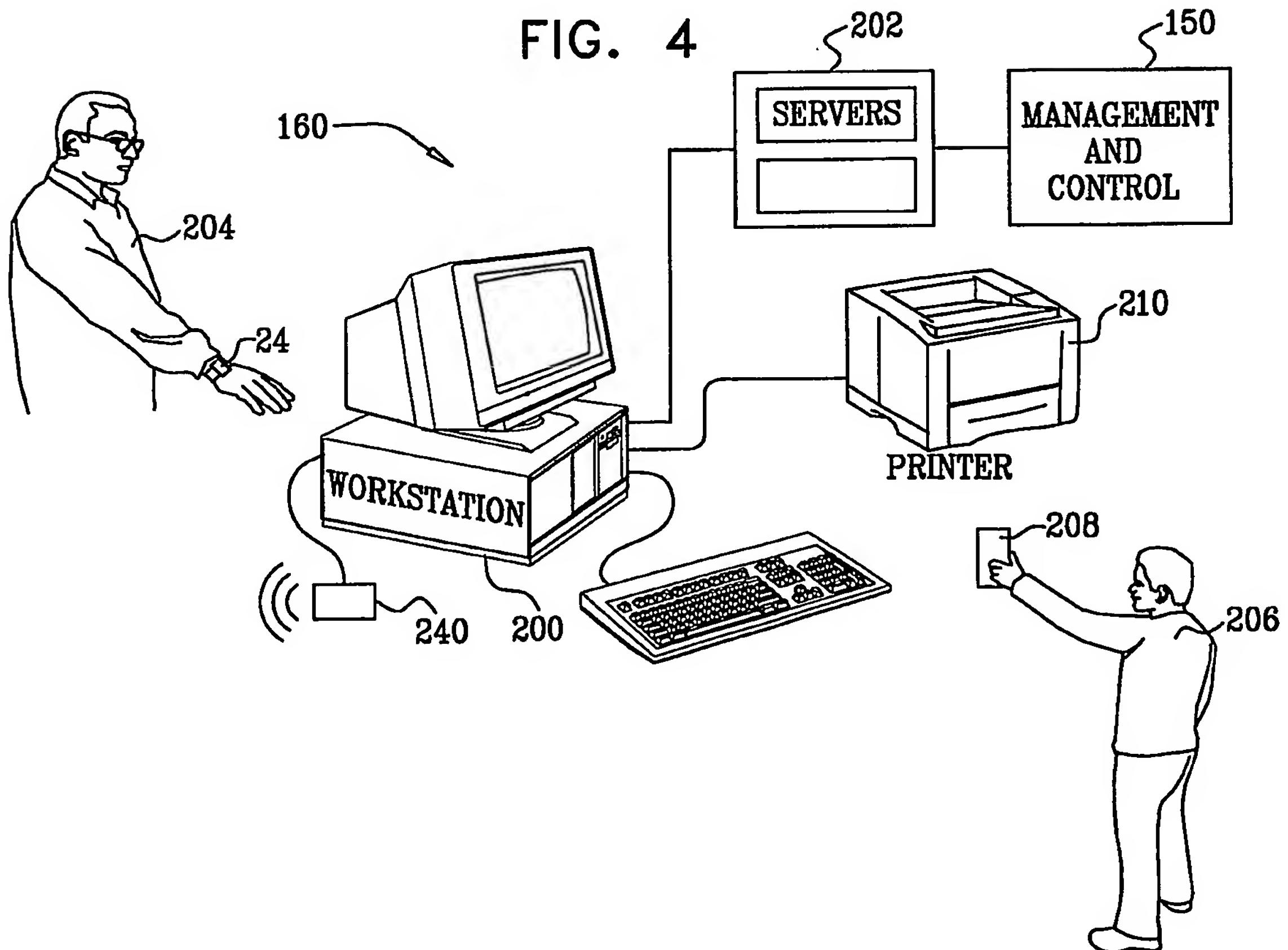
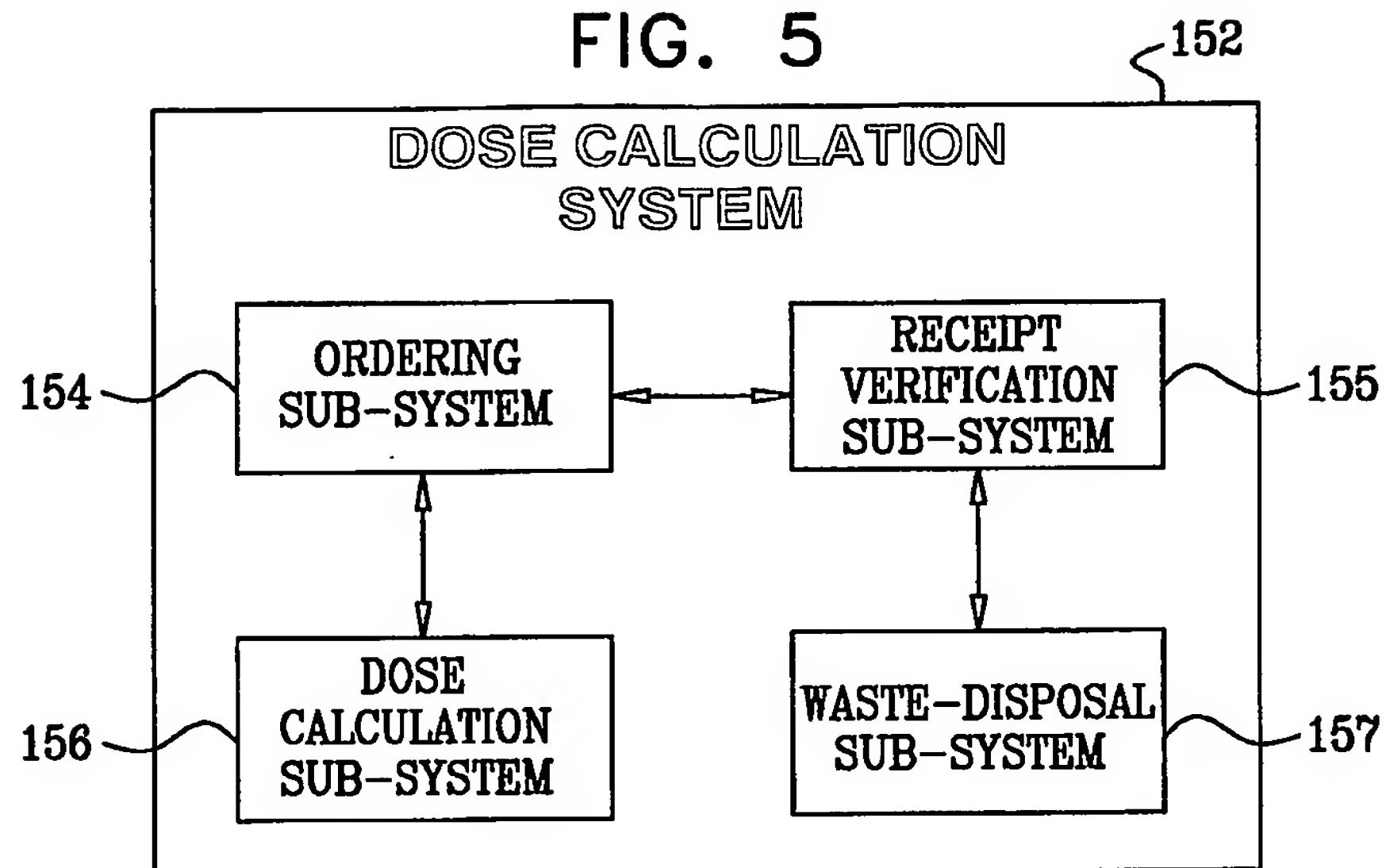


FIG. 4



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FIG. 5



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FIG. 6A

	REST PHASE			STRESS PHASE				
	INJECTION RP	DOSE [mCi]	WAITING TIME [MIN]	ACQUISITION DURATION [MIN]	INJECTION RP	DOSE [mCi]	WAITING TIME [MIN]	GATED ACQUISITION DURATION [MIN]
SINGLE ISOTOPE/ LOW DOSE/FAST IMAGING	TL	<0.3	2	15	EXERCISE	TL	<3	10-15
DUAL ISOTOPE/ LOW DOSE/FAST IMAGING	TL	<0.3	2	15	EXERCISE	Tc- MBI	30	30-60
GATED REST THALLIUM (STUNNING)	TL	1.5	2	5 (GATED)	EXERCISE	Tc- MBI	30	30-60
THALLIUM STRESS PERFUSION	Tc- MBI	3	30	1.5	PHARMA	TL	3	0 (DYNAMIC)
SIMULTANEOUS DUAL ISOTOPE STRESS PERfusion	Tc- MBI	3	20		EXERCISE/PHARMA	TL	3	10 (DYNAMIC)
DYNAMIC IMAGING	TL	0.3			PHARMA (ADENOSINE)	TL	3	10 (DYNAMIC)

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FIG. 6B

NO. PROTOCOL NAME	KEY FEATURES AND PROPERTIES	ADMINISTRATION PARAMETERS			DETECTOR PARAMETERS
		DOSE (mCi)	INJECTION PROFILE	INJECT TO ACQUISITION TIME	
A CARDIAC MAPPING	MIIBI-Tc, FAST, BEFORE LIVER UPTAKE	20-40	BOLUS	2 MIN, OR ADMIN UNDER THE CAMERA	140 KeV / 15%
B CARDIAC MAPPING	MIIBI-Tc AFTER LIVER UPTAKE	20-40	BOLUS	30+ MIN	140 KeV / 15%
C CARDIAC MAPPING	SIMULTANEOUS FAST DUAL-ISOTOPE TL-201+ LOW DOSE MIIBI-Tc	TL-201: 3.5-5; MIIBI-Tc-99m: 4-8	2 BOLUS (BEFORE AND AT PEAK STRESS)	TL INJECTED PREVIOUSLY AT REST, TC UNDER CAMERA OR 2 MIN	Tc-140 KeV, Tl-72 KeV / 15%
D CARDIAC MAPPING	SIMULTANEOUS DUAL-ISOTOPE TL-201+ LOW DOSE MIIBI-Tc	TL-201: 3.5-5; MIIBI-Tc-99m: 4-8	2 BOLUS (BEFORE AND AT PEAK STRESS)	SAME AS ONE OF FIRST 2 CARDIAC MAPPING PROTOCOLS	Tc-140 KeV, Tl-72 KeV / 15%
E CARDIAC MAPPING	SIMULTANEOUS DUAL-ISOTOPE FULL TL-201+ FULL DOSE MIIBI-Tc	TL-201: 3.5-5; MIIBI-Tc-99m: 20-40	2 BOLUS (BEFORE AND AT PEAK STRESS)	SAME AS ONE OF PROTOCOLS A OR B	Tc-140 KeV, Tl-167 KeV / 10%
F CARDIAC MAPPING - UNDERWEIGHT (BMI<18.5)	MIIBI-Tc-99m AFTER LIVER UPTAKE	15-20	BOLUS	30+ MIN	140 KeV / 15%
G1 CARDIAC MAPPING - NORMAL (18.6<BMI<24.9)	MIIBI-Tc-99m AFTER LIVER UPTAKE	20-30	BOLUS	30+ MIN	140 KeV / 10%
G2 CARDIAC MAPPING - OVERWEIGHT (25<BMI<29.9)	MIIBI-Tc-99m AFTER LIVER UPTAKE	30-35	BOLUS	30+ MIN	140 KeV / 10%

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FIG. 6C

NO.	TOTAL SCAN TIME	SCANNING PARAMETERS				ANALYSIS PARAMETERS		
		COLUMNS DIFFERENCES / UNIFORM SCAN	ANGULAR RANGE	TOTAL # ANGULAR ORIENT- TATIONS	ANGULAR STEP / INTERLACE	DWELL TIME	GATED ANALYSIS OF VOLUMES	ANALYSIS ALGORITHM / PARAMETERS
A	120 SEC	a) 4 X OUTER b) 6 X INNER	a) 40-60 DEG b) 90-120 DEG	120X10	a) 0.3-0.5 DEG b) 0.75-1 DEG	1 SEC	YES, 16-32 FRAMES	INTENSITY IMAGE, EJECTION FRACTION
B	120 SEC	a) 4 X OUTER b) 6 X INNER	a) 40-60 DEG b) 90-120 DEG	120X10	a) 0.3-0.5 DEG b) 0.75-1 DEG	1 SEC	YES, 16-32 FRAMES	INTENSITY IMAGE, EJECTION FRACTION
C	120 SEC	a) 4 X OUTER b) 6 X INNER	a) 40-60 DEG b) 90-120 DEG	120X10	a) 0.3-0.5 DEG b) 0.75-1 DEG	1 SEC	YES, 16-32 FRAMES	INTENSITY IMAGE, EJECTION FRACTION
D	120 SEC	a) 4 X OUTER b) 6 X INNER	a) 40-60 DEG b) 90-120 DEG	120X10	a) 0.3-0.5 DEG b) 0.75-1 DEG	1 SEC	YES, 16-32 FRAMES	INTENSITY IMAGE, EJECTION FRACTION
E	UP TO 1200 SEC	a) 4 X OUTER b) 6 X INNER	a) 40-60 DEG b) 90-120 DEG	240X10	a) 0.15-0.25 DEG b) 0.375-0.5 DEG	5 SEC	YES, 16-32 FRAMES	INTENSITY IMAGE, EJECTION FRACTION
F	90 SEC	a) 4 X OUTER b) 6 X INNER	a) 20-35 DEG b) 45-60 DEG	60X10	a) .3-.75 DEG b) 0.75-1 DEG	1 SEC	YES, 16-32 FRAMES	INTENSITY IMAGE, EJECTION FRACTION
G1	120 SEC	a) 4 X OUTER b) 6 X INNER	a) 30-45 DEG b) 75-90 DEG	120X10	a) 0.5-0.75 DEG b) 0.625-1 DEG	1.5 SEC	YES, 16-32 FRAMES	INTENSITY IMAGE, EJECTION FRACTION
G2	120 SEC	a) 4 X OUTER b) 6 X INNER	a) 40-60 DEG b) 90-120 DEG	120X10	a) 0.3-0.5 DEG b) 0.75-1 DEG	2 SEC	YES, 16-32 FRAMES	INTENSITY IMAGE, EJECTION FRACTION

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FIG. 6D

NO.	PROTOCOL NAME	KEY FEATURES AND PROPERTIES	ADMINISTRATION PARAMETERS		DETECTOR PARAMETERS
			DOSE (mCi)	INJECTION PROFILE	
H	CARDIAC MAPPING - OBESE (BMI>30)	MIBI-TC AFTER LIVER UPTAKE	35-40	BOLUS	30+ MIN 140 KeV / 6%
I	CARDIAC DYNAMIC MAPPING	TEBOROXIME-TC	20-40	BOLUS	-1 MIN (IMAGE BEFORE INJECT), OR SIMULTANEOUSLY WITH INJECT 140 KeV / 15%
J	CARDIAC DYNAMIC MAPPING (2-STEP)	TEBOROXIME-TC	20-40	(i) INITIAL SMALL BOLUS FOR IDENTIFYING ROI, (ii) FULL BOLUS FOR DYNAMIC STUDY	(i) 5+ MIN (ii) -1 MIN (IMAGE BEFORE INJECT) 140 KeV / 15%
K	TUMOR SCAN (MULTIPLE BODY SEGMENTS - HEAD TO LEGS)	MDP-TC-99M AFTER LIVER UPTAKE	20-40	BOLUS	30+ MIN 140 KeV / 15%
L	TUMOR SCAN (MULTIPLE BODY SEGMENTS - HEAD TO LEGS), FOCUSED SCAN	MDP-TC-99M AFTER LIVER UPTAKE	20-40	BOLUS	30+ MIN 140 KeV / 15%
M	TUMOR SCAN WITH COCKTAIL (MULTIPLE BODY SEGMENTS - HEAD TO LEGS), FOCUSED SCAN	FDG (METABOLISM), MIBI-TC-99M AND TL (PERFUSION)	TL-201: 3.5-5; MIBI-TC-99M: 20-40; 18-F FDG 10-30	BOLUS	30+ MIN Tc-140 KeV, Ti-72 KeV, FDG 511 KeV / 10%

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FIG. 6E

SCANNING PARAMETERS				ANALYSIS PARAMETERS				
NO.	TOTAL SCAN TIME	COLUMNS DIFFERENCES / UNIFORM SCAN	ANGULAR RANGE	TOTAL # ANGULAR ORIENT- TATIONS	ANGULAR STEP / INTERLACE	DWELL TIME	GATED ANALYSIS OF VOLUMES	ANALYSIS ALGORITHM / PARAMETERS
H	180 SEC	a) 4 X OUTER b) 6 X INNER	a) 40-60 DEG b) 90-120 DEG	160X10	a) 0.25-0.375 DEG b) 0.6-0.75 DEG	1.2 SEC	YES, 8-16 FRAMES	INTENSITY IMAGE, EJECTION FRACTION
I	<= 600 SEC	a) 2 X OUTER b) 8 X INNER	a) 40-60 DEG b) 90-120 DEG	600X10	a) continuous b) continuous INTERLACED SCAN	1 SEC	YES, 8 FRAMES	KINETIC PARAMETERS, PREDEFINED PATHOLOGICAL VALUES
J	(i) 60 SEC FOR IDENTIFYING ROI (ii) 600 SEC (iii) 600 SEC DYNAMIC STUDY	a) 2 X OUTER b) 8 X INNER	a) 40-60 DEG b) 90-120 DEG	(i) 60X10 (ii) 600X10	(i) a) 0.75-1 DEG b) 0.75-0.75-1 DEG (ii) a) continuous b) continuous INTERLACED SCAN	1 SEC	YES, 8 FRAMES	KINETIC PARAMETERS, PREDEFINED PATHOLOGICAL VALUES
K	240 SEC PER BODY SEGMENT	16	40-60 DEG	120X16	0.3-0.5 DEG	2 SEC	NO	INTENSITY IMAGE, PREDEFINED PATHOLOGICAL VALUES
L	(i) 120 SEC PER BODY SEGMENT (ii) 60 SEC PER ROI	16	(i) 45-60 DEG (ii) 15-20 DEG	(i) 120X16 (ii) 60x16	(i) 0.375-0.5 DEG (ii) 0.25-0.3	1 SEC	NO	INTENSITY IMAGE, PREDEFINED PATHOLOGICAL VALUES
M	(i) 120 SEC PER BODY SEGMENT (ii) 60 SEC PER ROI	16	(i) 45-60 DEG (ii) 15-20 DEG	(i) 120X16 (ii) 60x16	(i) 0.375-0.5 DEG (ii) 0.25-0.4	1 SEC	NO	INTENSITY IMAGE, PREDEFINED PATHOLOGICAL VALUES

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FIG. 7

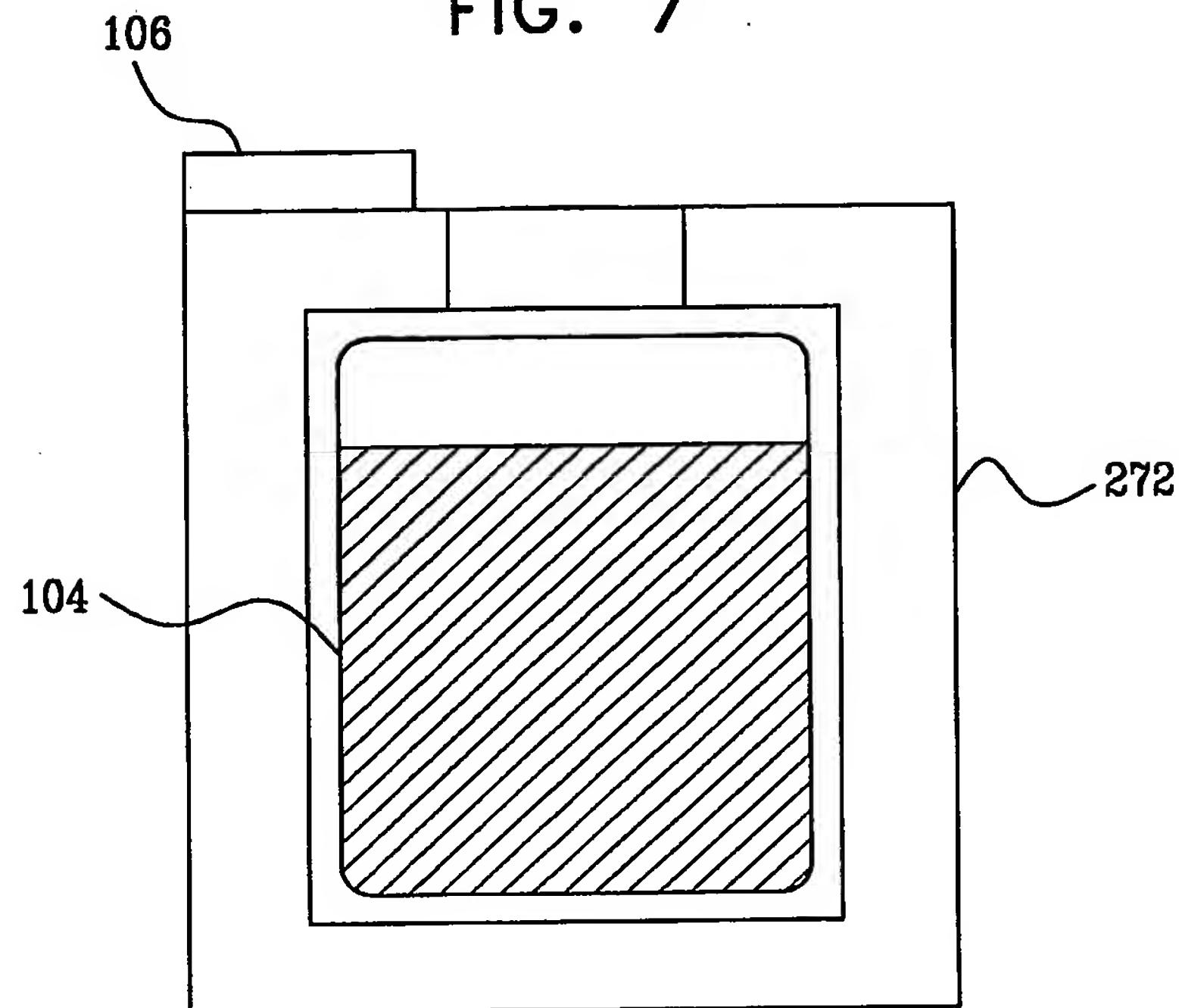
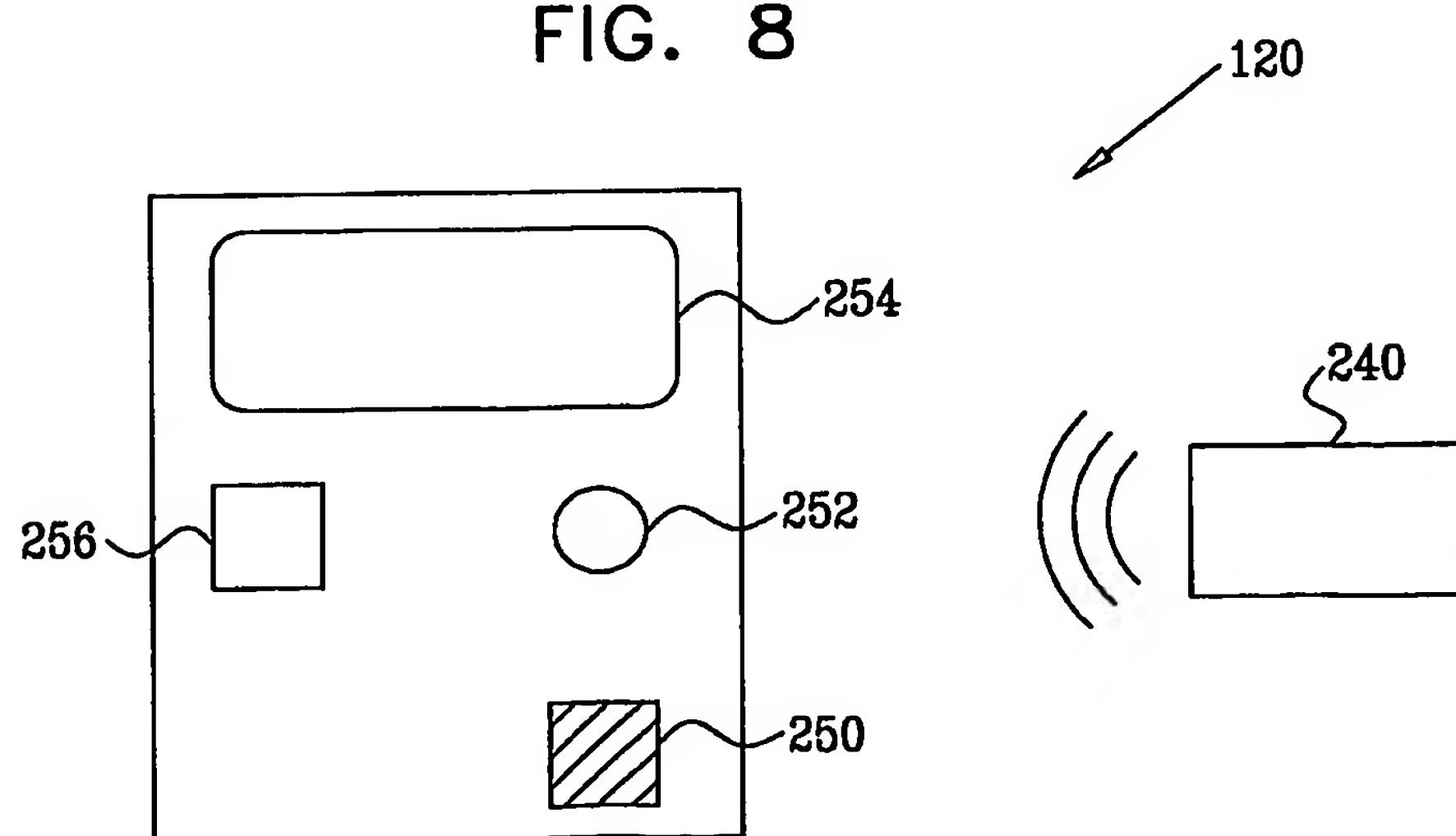


FIG. 8



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FIG. 9A

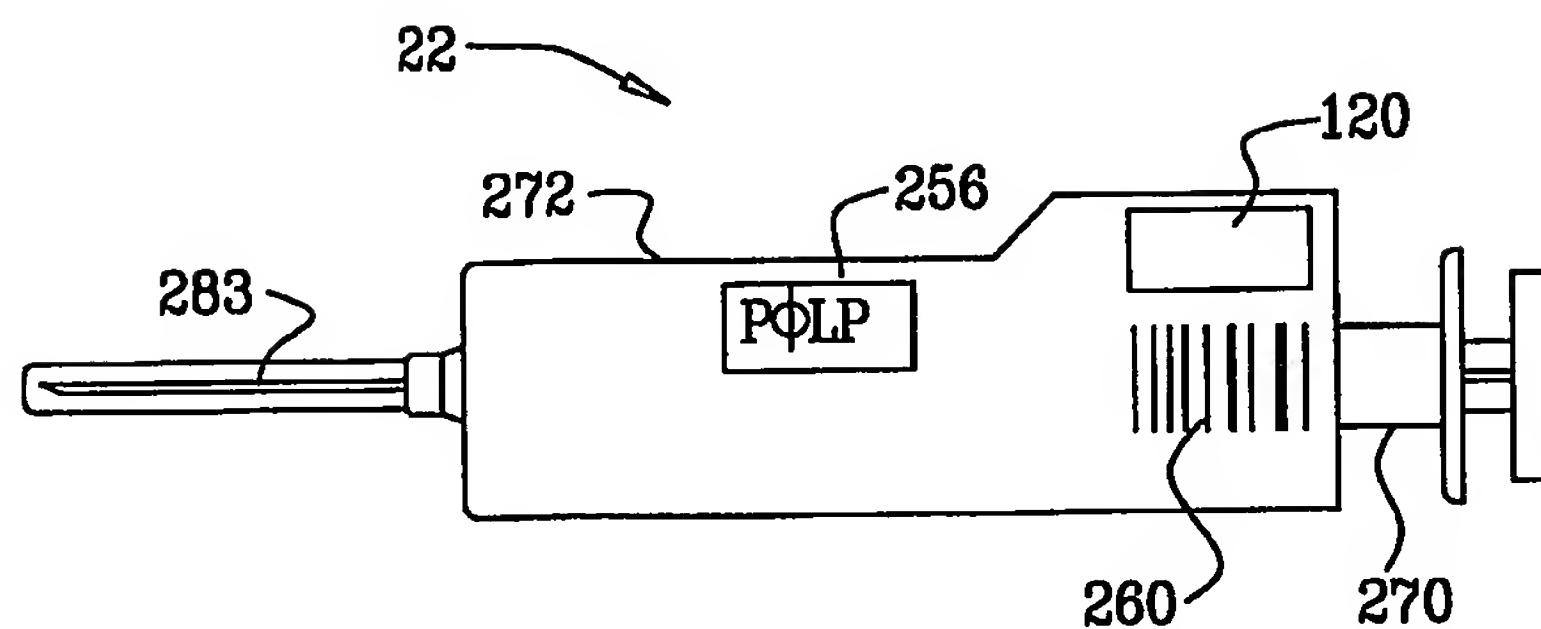


FIG. 9B

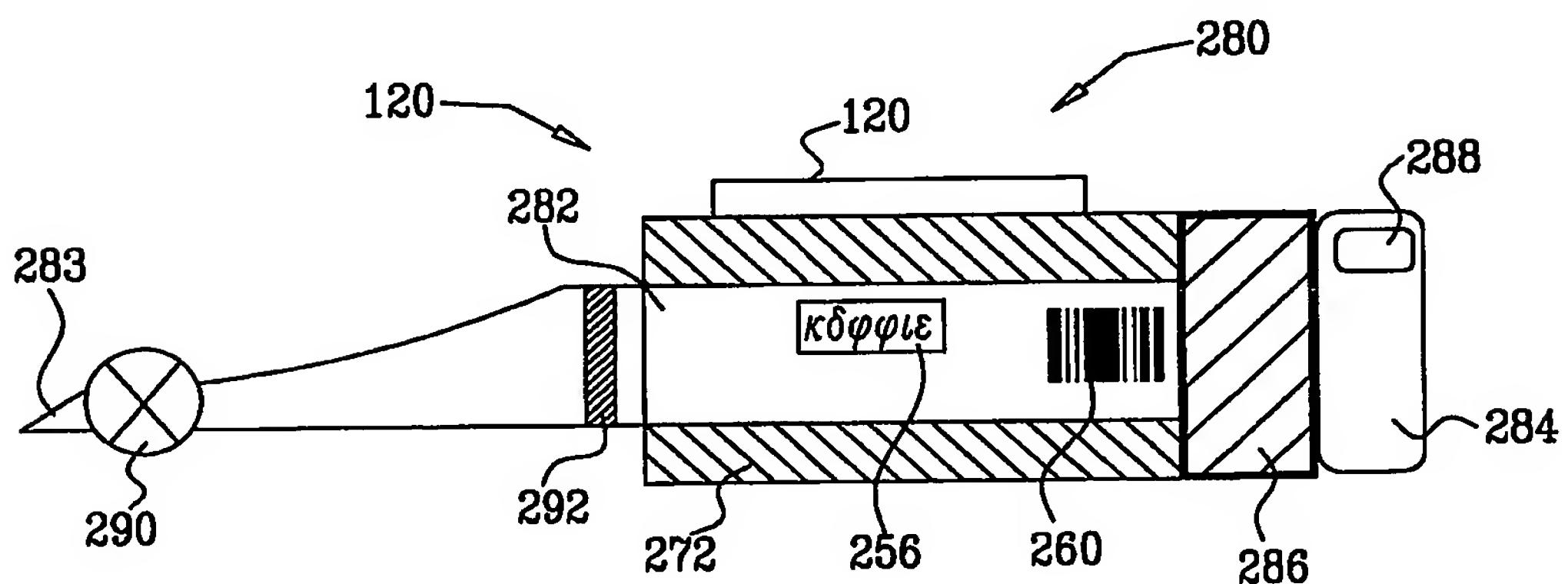
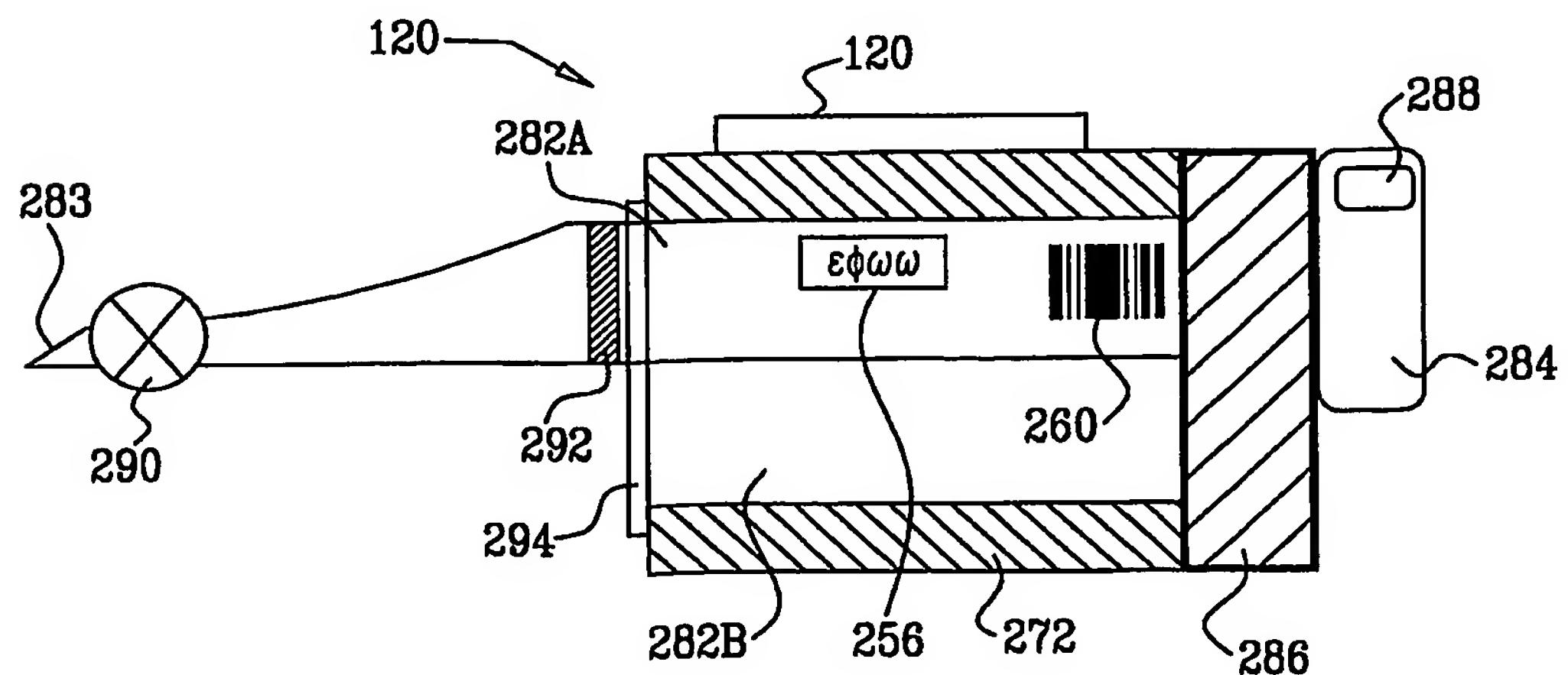


FIG. 9C



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FIG. 9D

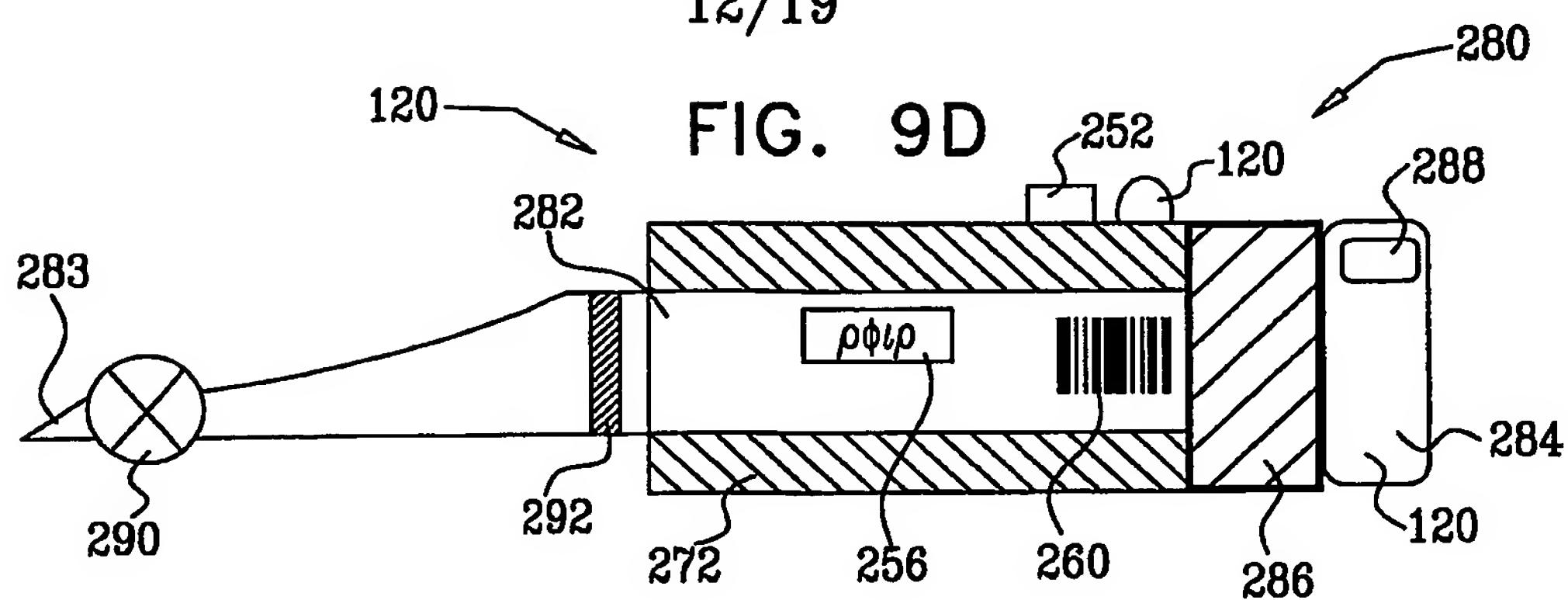


FIG. 9E

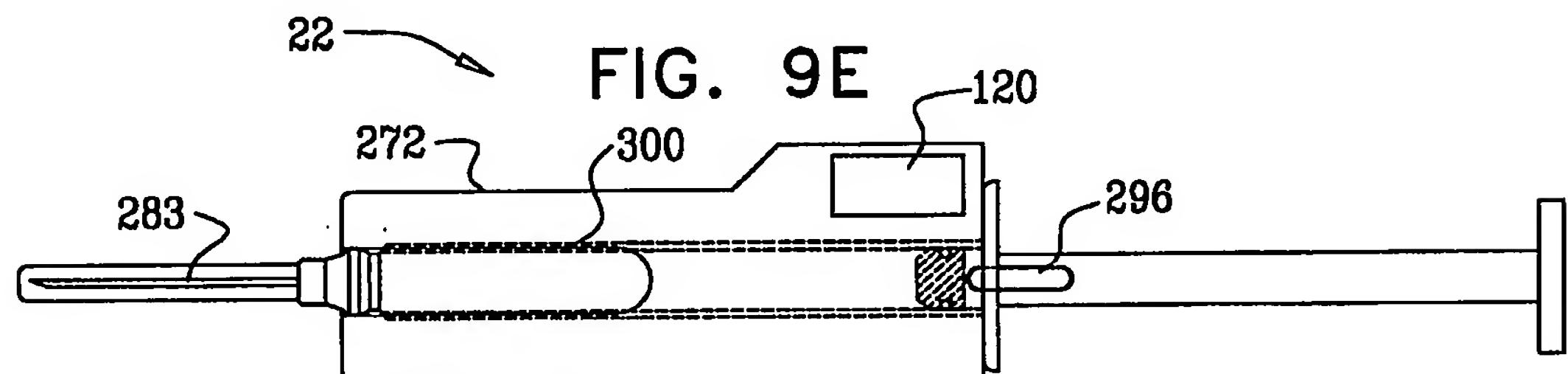


FIG. 9F

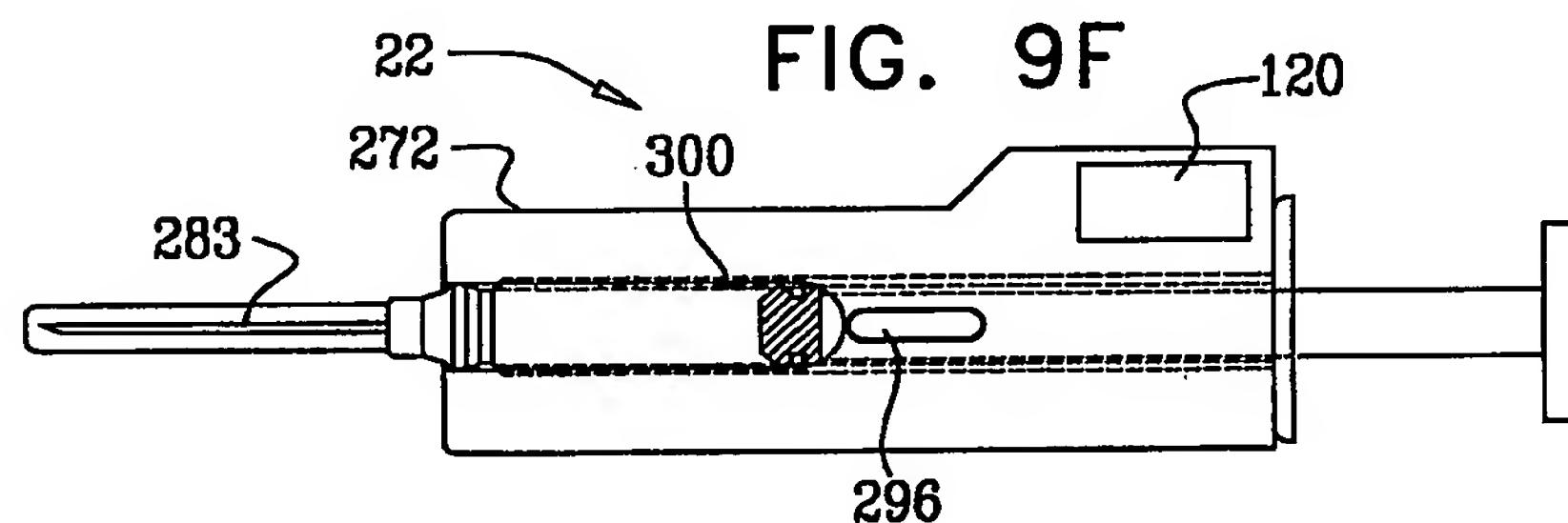


FIG. 9G

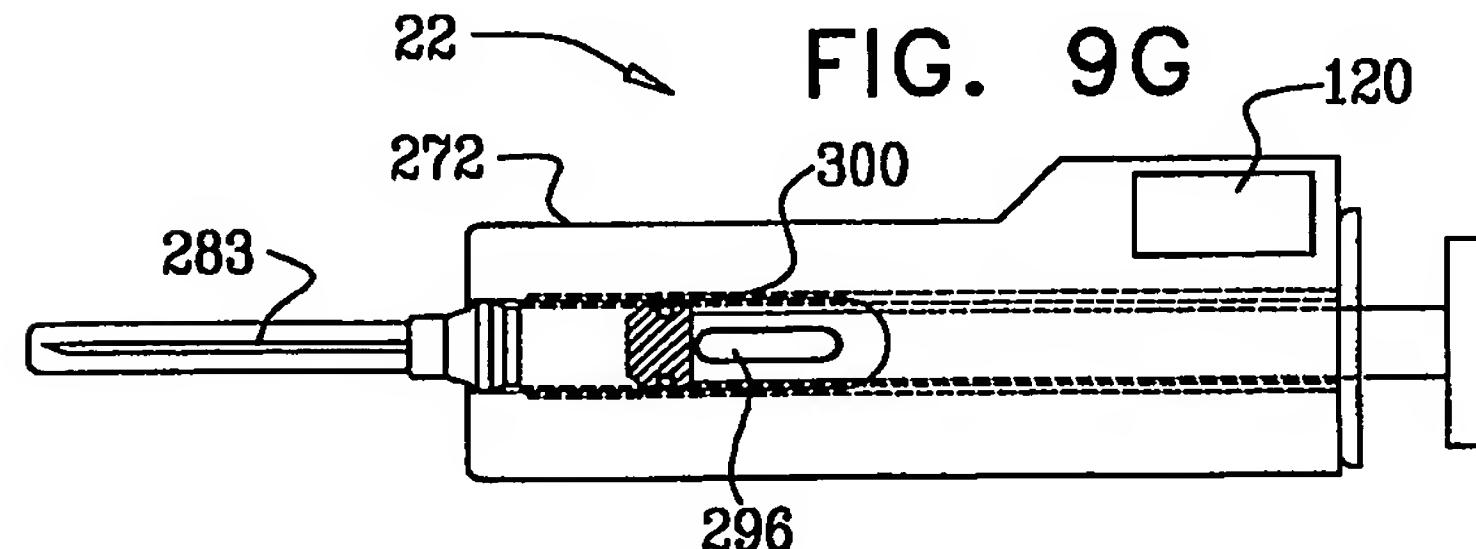


FIG. 9H

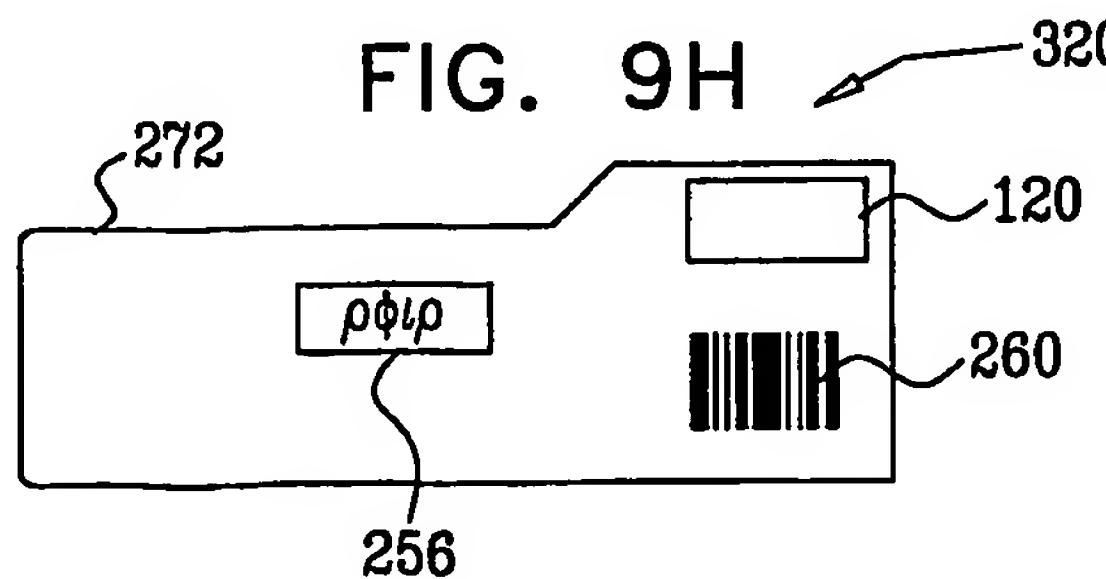


FIG. 10

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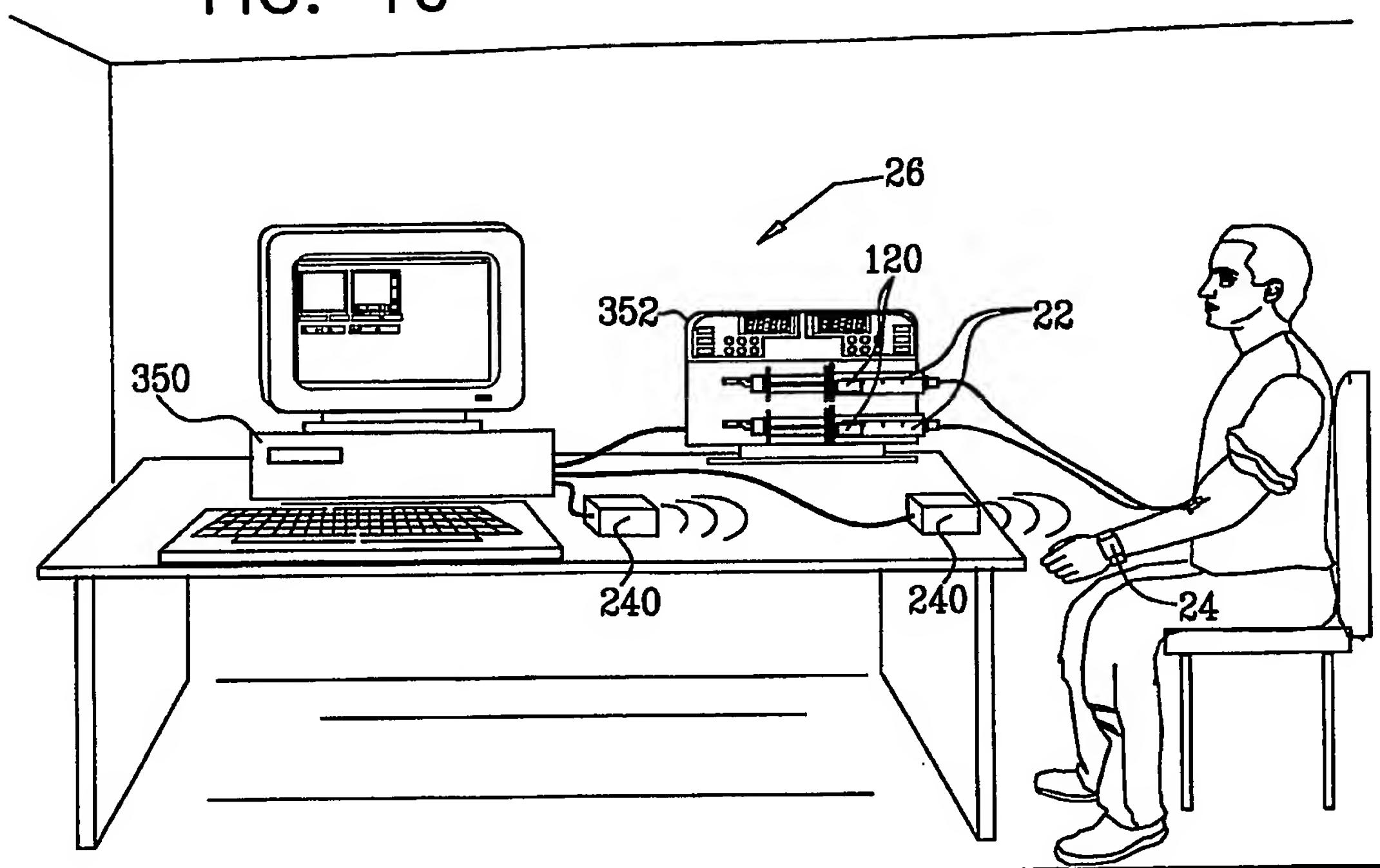


FIG. 11

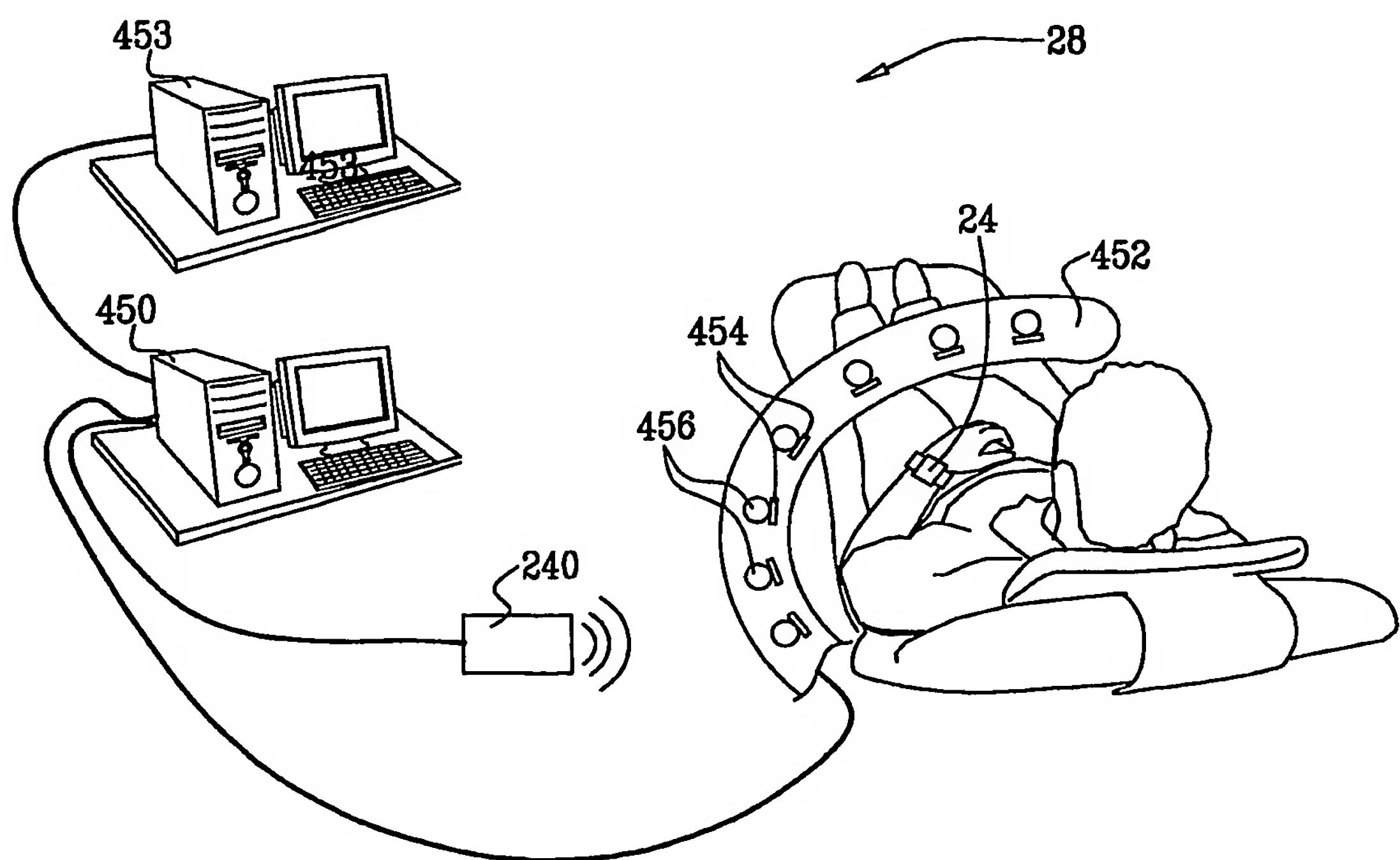
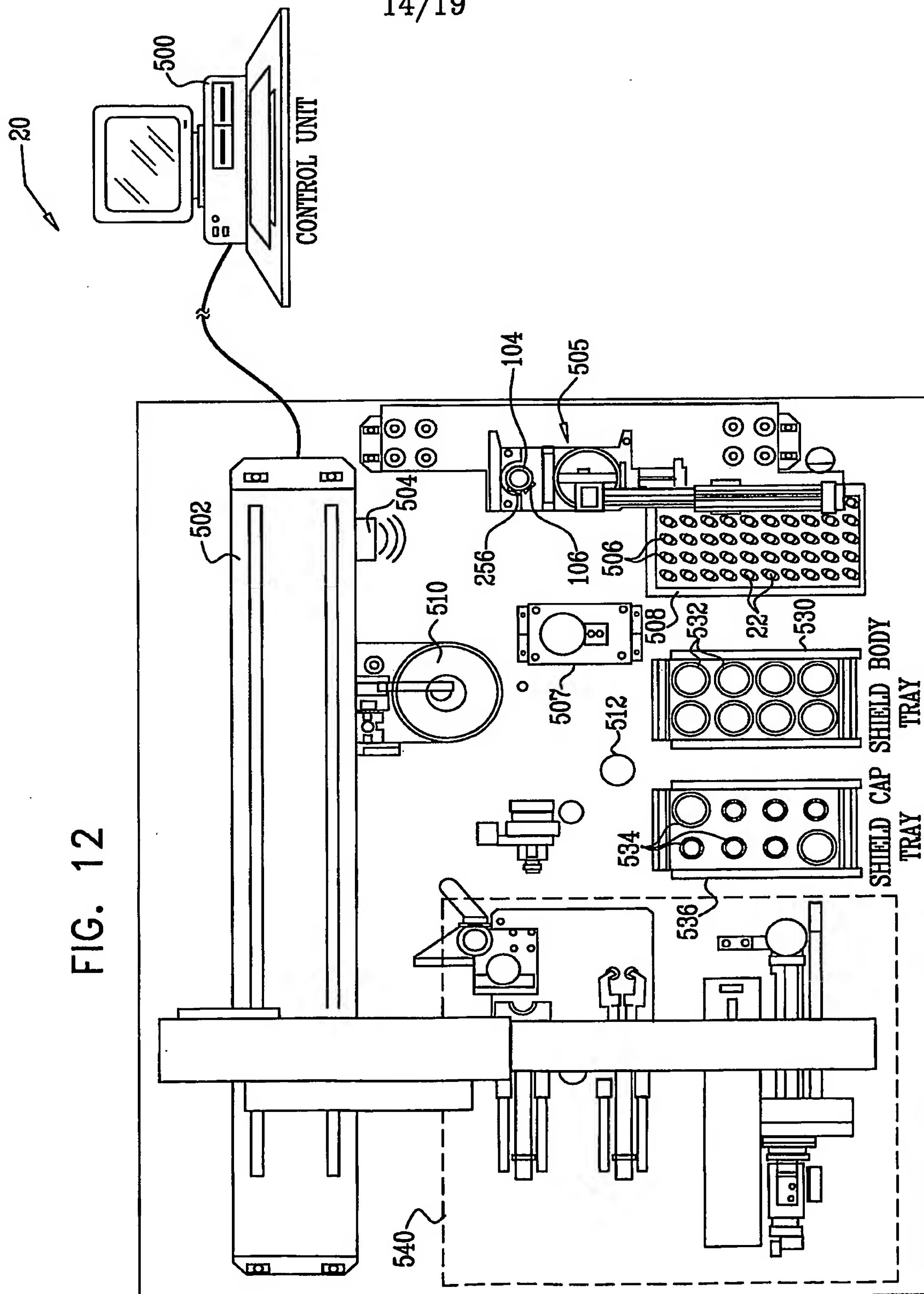


FIG. 12

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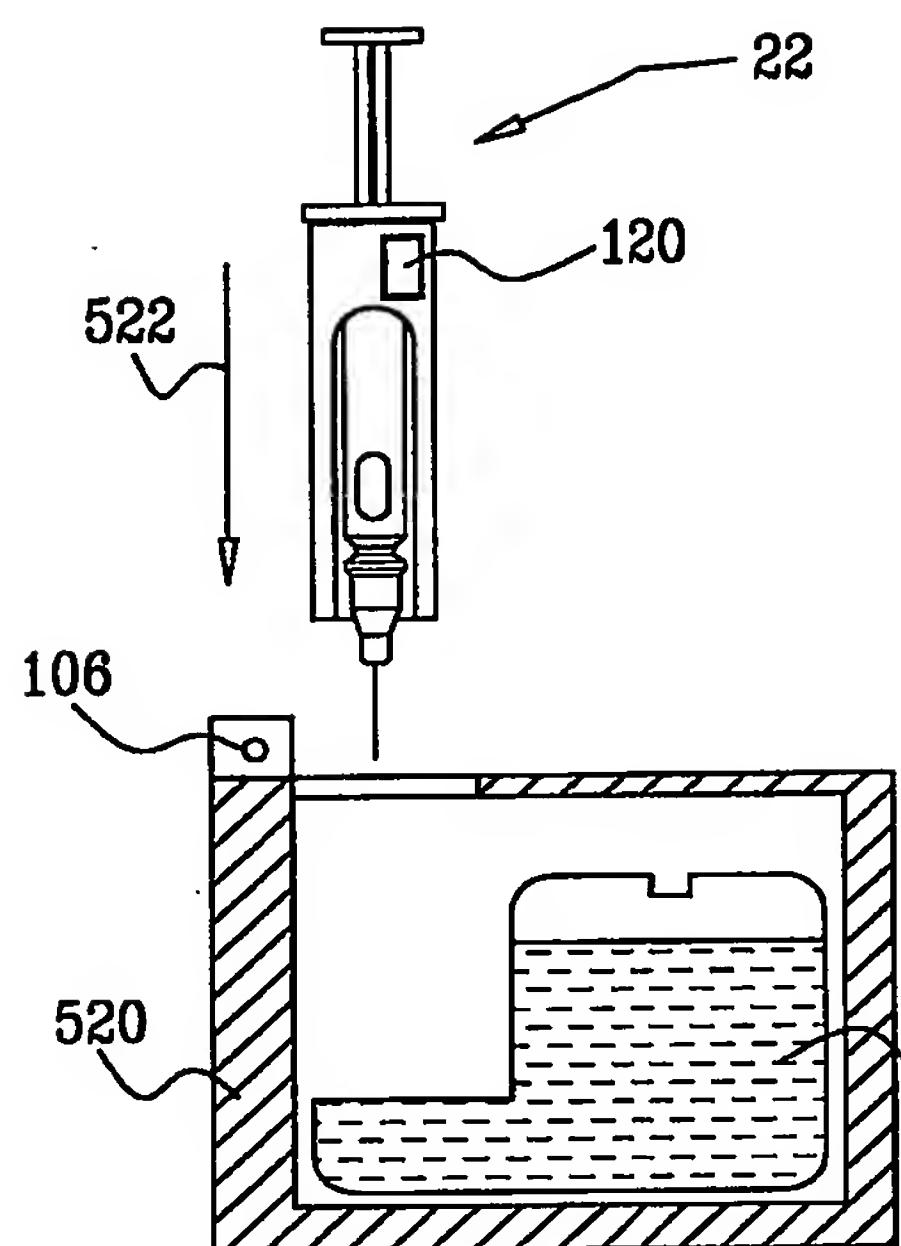


FIG. 13A

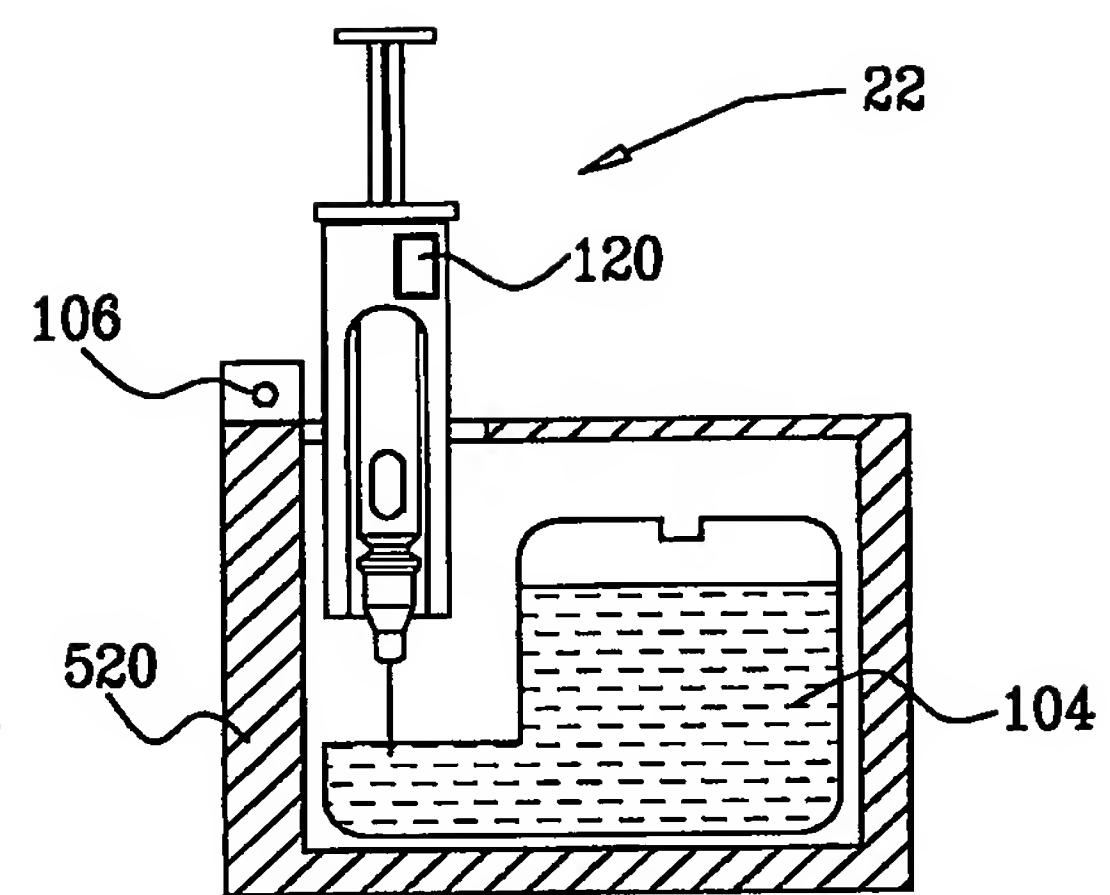


FIG. 13B

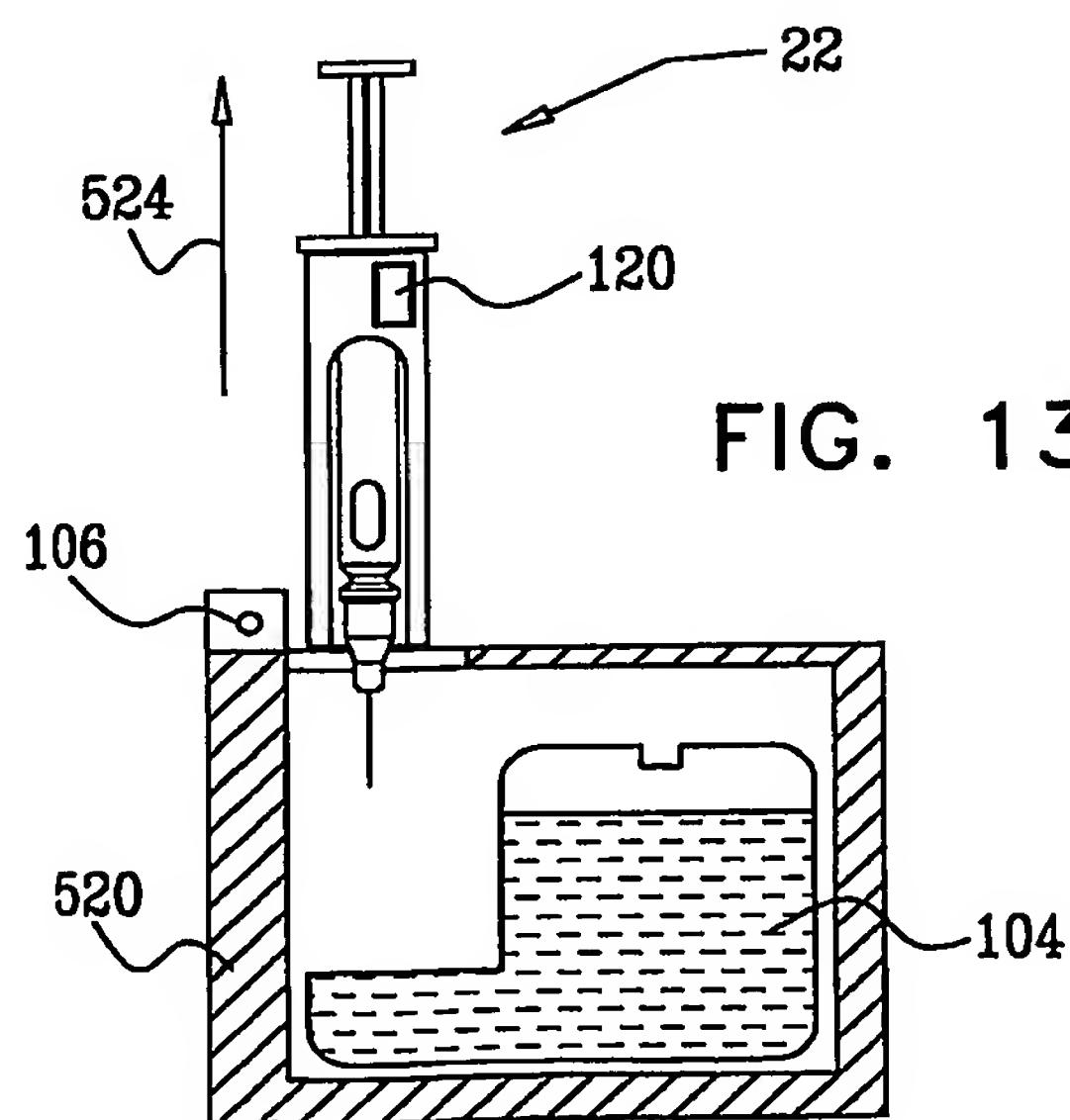
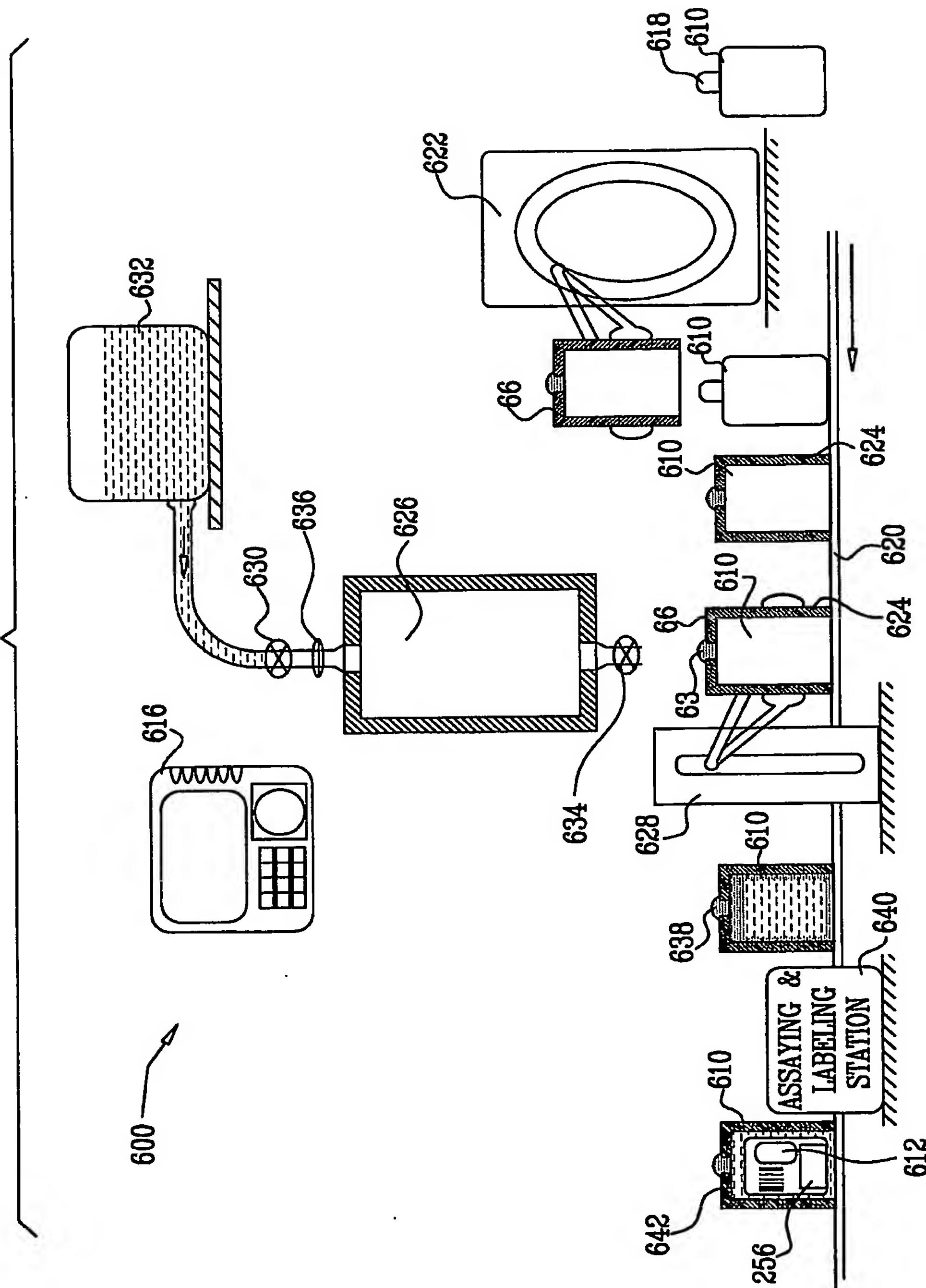


FIG. 13C

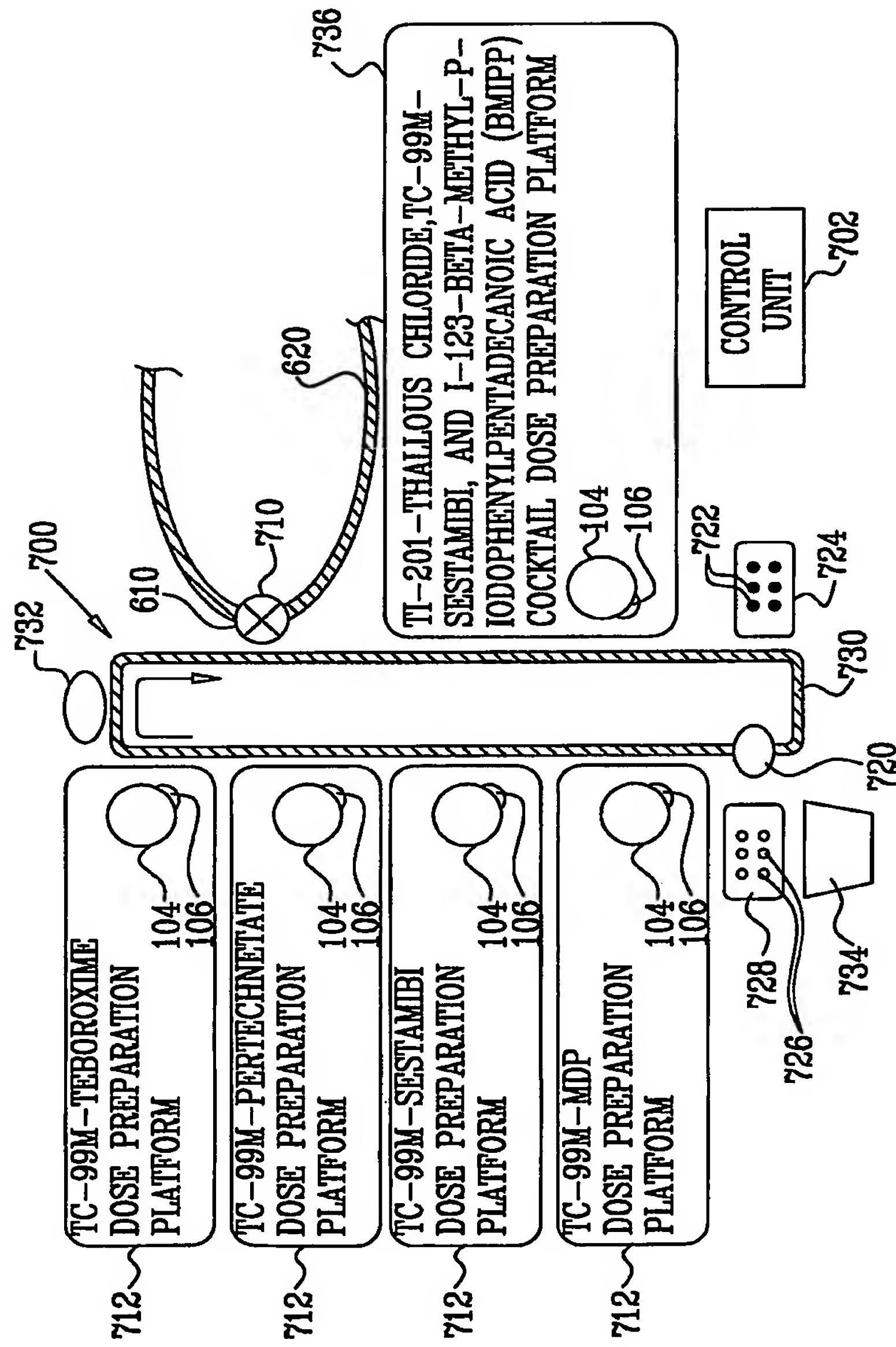
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FIG. 14



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FIG. 15



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FIG. 16A

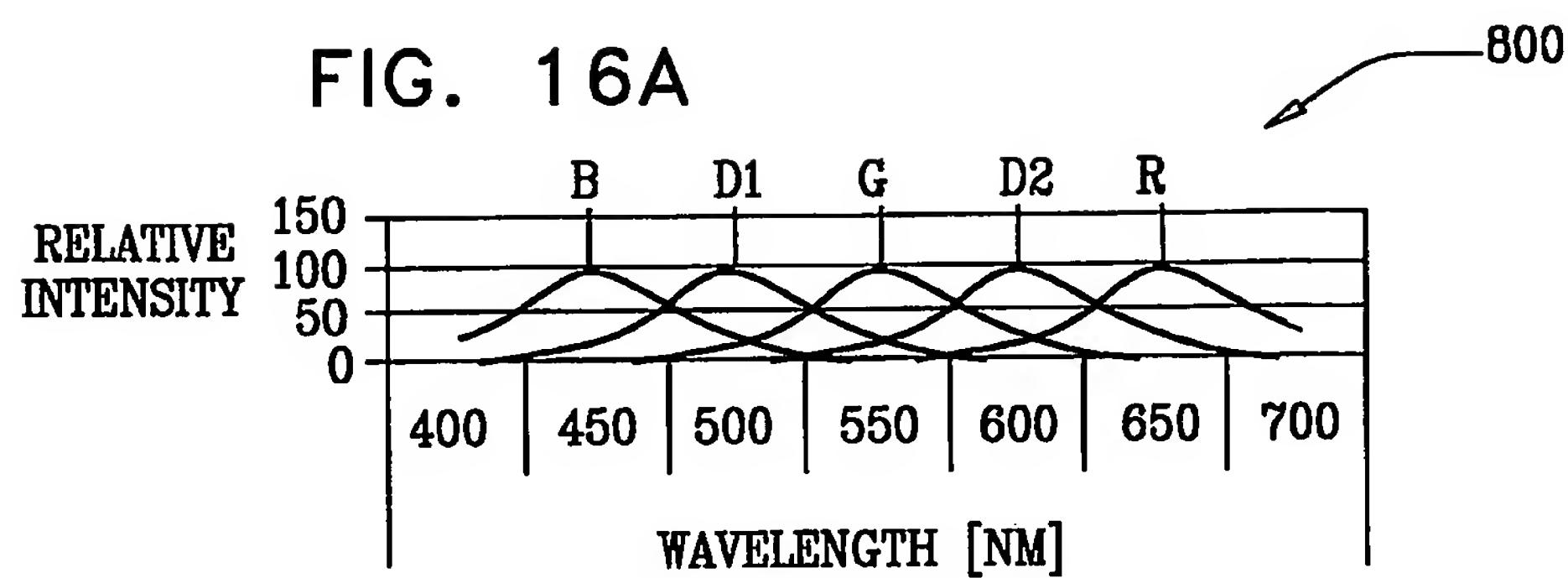
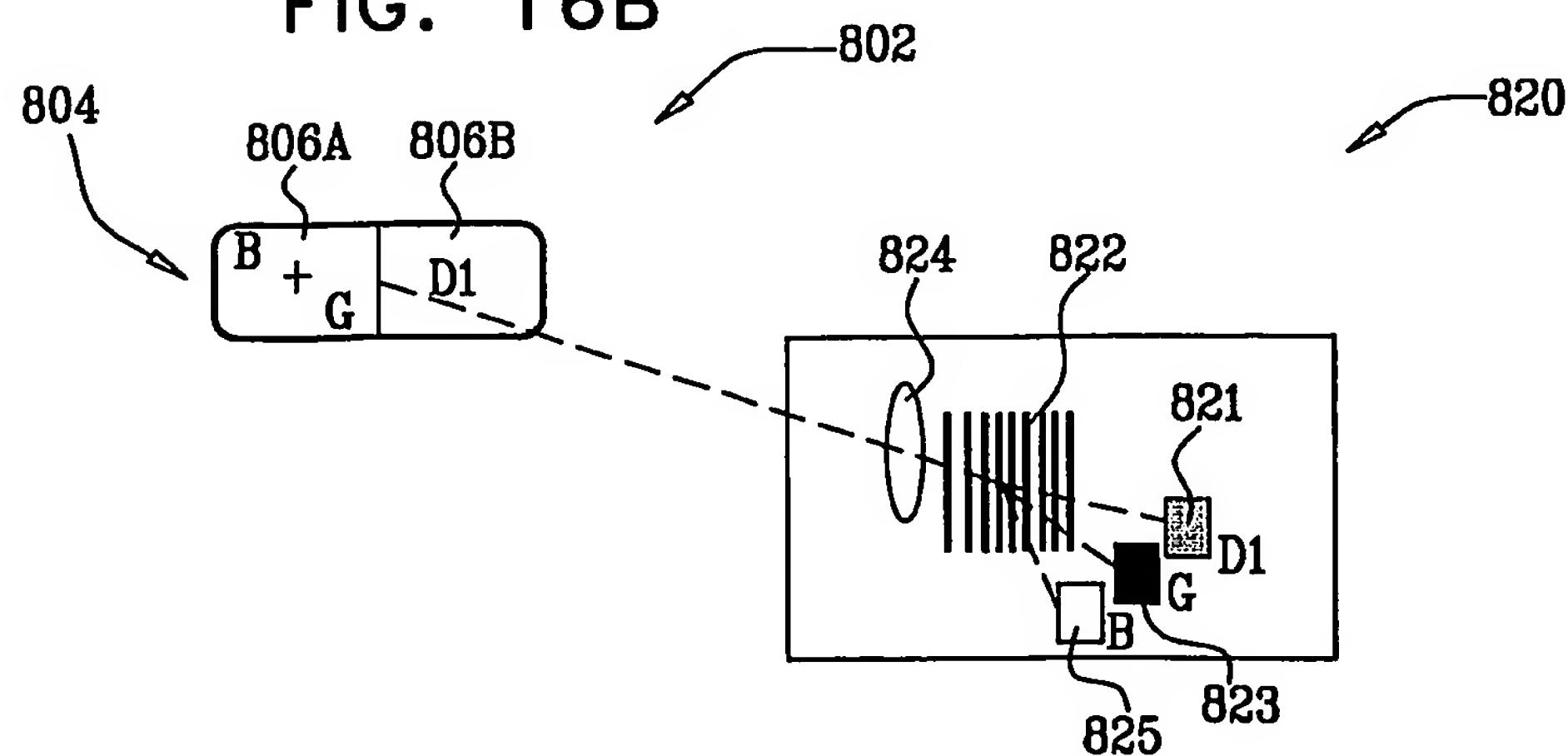


FIG. 16B



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FIG. 17

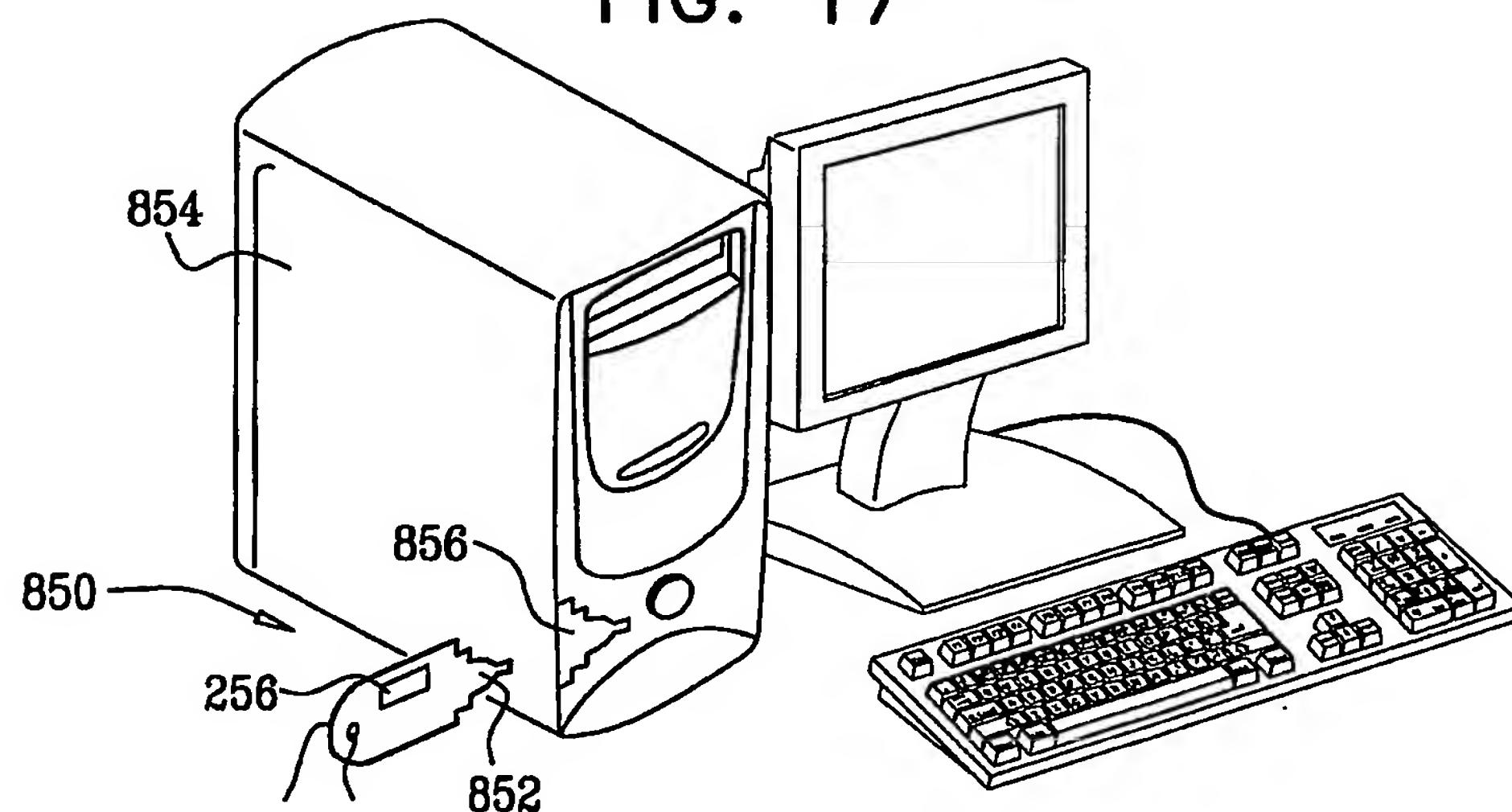
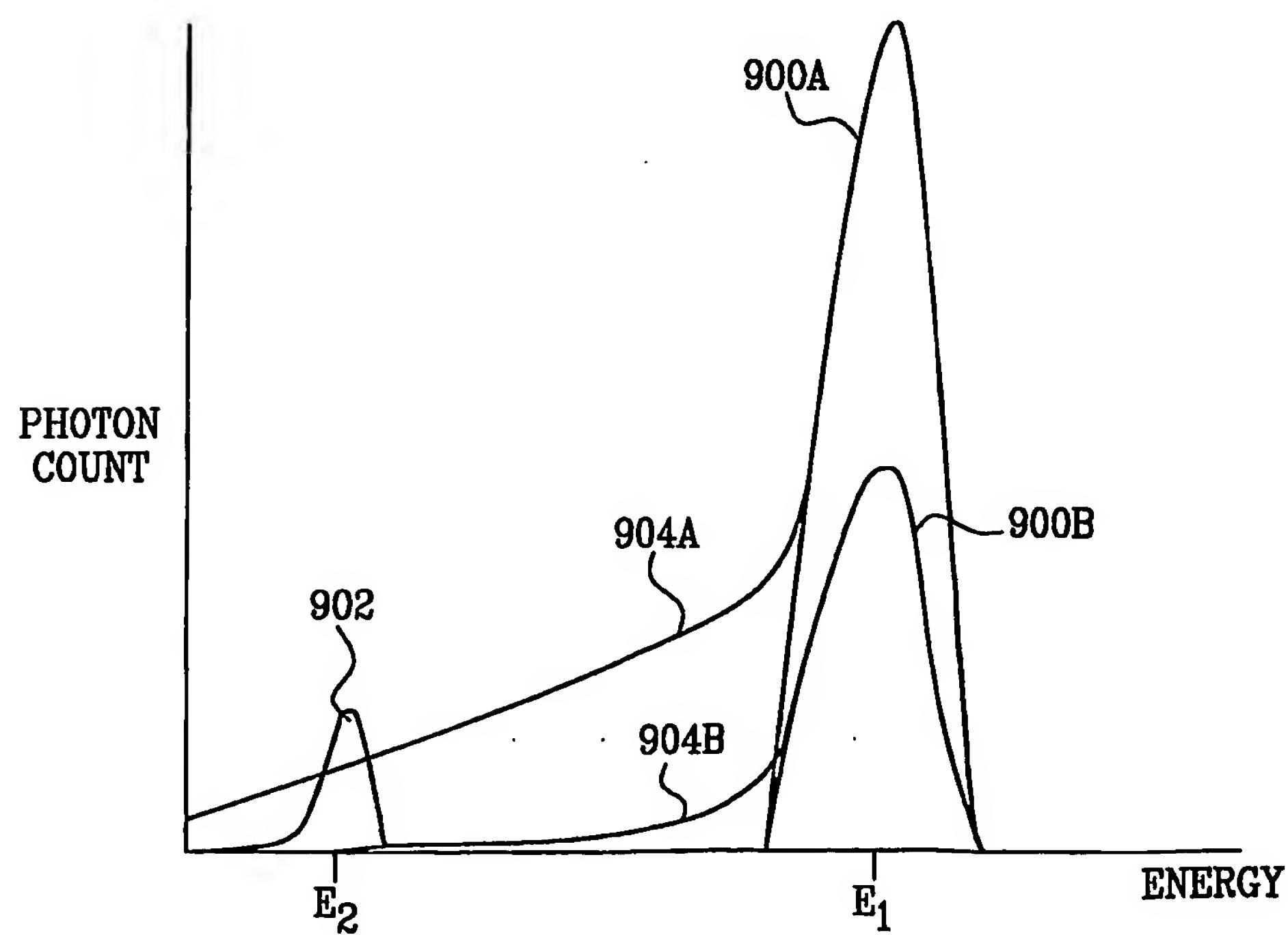


FIG. 18



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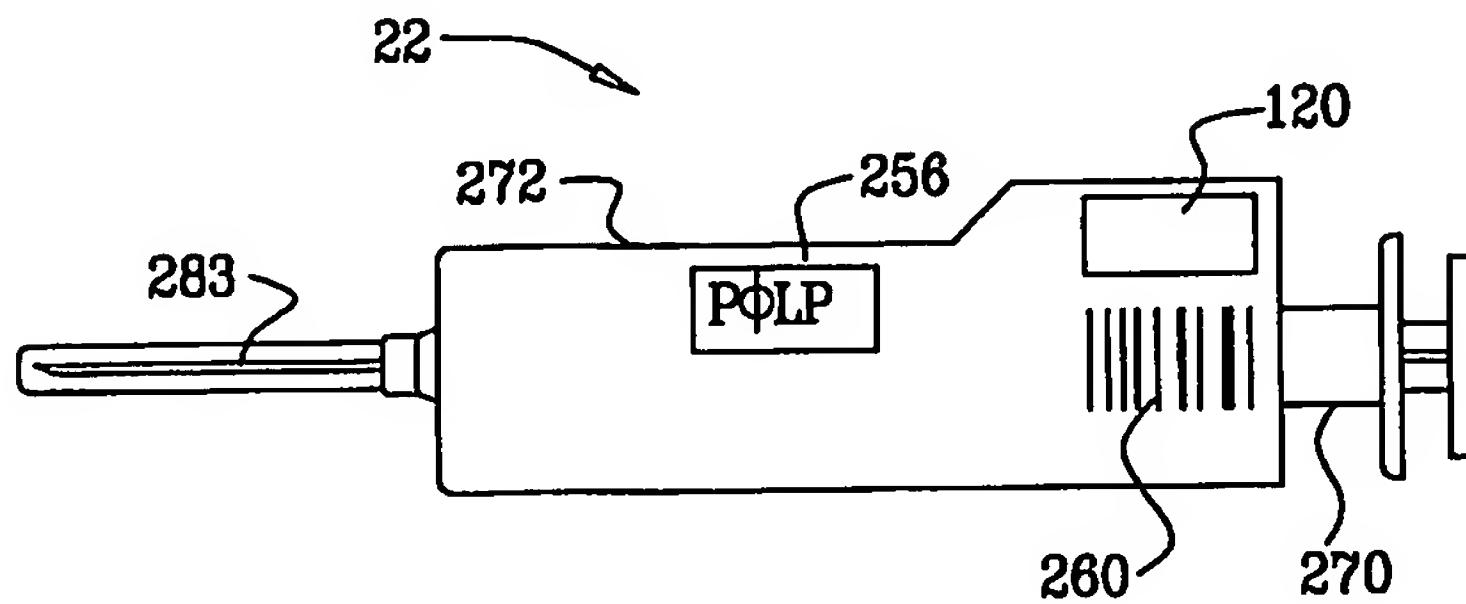
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[Continued on next page]

(54) Title: UNIFIED MANAGEMENT OF RADIOPHARMACEUTICAL DISPENSING, ADMINISTRATION, AND IMAGING

WO 2006/129301 A3



(57) Abstract: Apparatus is provided for use with at least one labeled radiopharmaceutical agent, the apparatus including a container (22) containing the at least one labeled radiopharmaceutical agent, and a portable computer-communicatable data carrier (120, 24) associated with the container (22), the data carrier (120, 24) containing imaging protocol information for use with the at least one labeled radiopharmaceutical agent. Other embodiments are also described.

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International application No.

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USPC: 705/2;600/436

According to International Patent Classification (IPC) or to both national classification and IPC

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0107698 A1 (POWERS et al) 19 May 2005 (19.05.2005), (Figures 1, 21-23; pars. 75, 102-109)	1-190
Y	US 6401071 B1 (HOGAN) 4 JUNE 2002 (04.06.2002), col. 3, lines 23-col. 10, line 39	1-190
Y	US 6149574 A (TRAUTHEN et al) 21 November 2000 (21.11.2000), col. 5, line 1-col. 6, line 33; col. 12, lines 51-col. 13, line 3	1-190

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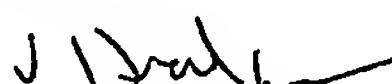
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